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169-69-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 417, 422, 423, 424, 431, 438, 447, 455, 457, 498

Office of the Secretary

45 CFR Part 155

[CMS-6098-P]

RIN 0938-AV97

Medicare, Medicaid, and Marketplace Programs; Comprehensive Regulations to Uncover Suspicious Healthcare (CRUSH)

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise provisions regarding provider enrollment, medical review, investigations, and other program integrity oversight provisions to greatly strengthen our ability to crush fraud, enhance program integrity efforts across Medicare, Medicaid, Children's Health Insurance Program, and the Marketplace and maximize regulatory authorities to address inappropriate payments.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by **[**Insert date 60 days after date of publication in the **Federal Register]**.

ADDRESSES: In commenting, please refer to file code CMS-6098-P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically*. You may submit electronic comments on this regulation to https://www.regulations.gov/docket/CMS-2026-0826. Follow the "Submit a comment" instructions.

2. *By regular mail*. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-6098-P,

P.O. Box 8013,

Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail*. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-6098-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Eli Boone, (227) 232-6768, or Katie O'Malley, (410) 786-8987.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: https://www.regulations.gov. Follow the search instructions on that website to view

public comments. CMS will not post on Regulations.gov public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at https://www.regulations.gov/.

I. Executive Summary

A. Purpose

On June 6, 2025, President Trump issued a Presidential Memorandum on Eliminating Waste, Fraud, and Abuse in Medicaid, expressing this Administration's commitment to preserve and protect the integrity of government programs. Similarly, President Trump, U.S. Department of Health and Human Services (HHS) Secretary Kennedy (the HHS Secretary), and Centers for Medicare & Medicaid Services (CMS) Administrator Oz (the CMS Administrator) have strongly demonstrated this Administration's dedication to crushing fraud in Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and the Marketplace. In alignment with this strategic objective, as well as in line with our statutory authorities to undertake rulemaking, CMS is issuing this proposed rule to solicit stakeholder feedback on proposed regulatory changes that would strengthen CMS' ability to address vulnerabilities that make Federal health programs attractive targets to fraudsters, with the ultimate goal of ensuring greater affordability and sustainability of these programs for generations to come.

B. Summary of the Major Provisions

1. Strengthening State Medicaid and CHIP Oversight

CMS intends to enhance Federal oversight of State Medicaid programs through proposed measures that would, if finalized as proposed, expand its authority to enforce program integrity and strengthen State accountability. These initiatives include: (1) facilitating States' ability to

rapidly suspend Medicaid payments based on credible allegations of fraud and strengthening State fraud reporting requirements; (2) establishing consistent provider identification requirements to increase State and Federal oversight capabilities; (3) increasing oversight of Medicaid and CHIP beneficiary eligibility determination errors; and (4) establishing strengthened State program integrity corrective action plan requirements to ensure compliance with Federal requirements. Additional provisions include:

- Requiring prompt reporting and return of Medicaid overpayments
- Enhancing managed care integrity reporting
- Broadening grounds for Medicaid provider denials and terminations
- Increasing data reporting on provider ownership
- Requiring electronic visit verification (EVV) data review for specific activities

Collectively, these enhancements aim to strengthen CMS' and States' ability to detect and address fraud, waste, and abuse in Medicaid and CHIP, while fostering improved collaboration between State and Federal efforts in program integrity.

In addition, we are including a request for information within this proposed rule. Specifically, CMS is requesting additional information and public comment regarding deductions from Medicaid payments for benefits such as union dues.

2. Reinvigorating the Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) Program and Introducing New Ways to Hold Plan Sponsors Accountable

CMS proposes MA RADV program reforms to ensure oversight of a program responsible for $21 billion per year in overpayments due to the improper inflation of beneficiary risk scores, and proposes provisions to make referrals of substantiated or suspicious fraud, waste, and abuse mandatory for MA organizations and Part D plan sponsors, as well as to expand the required reporting of credible allegation of fraud payment suspensions by pharmacies to all provider and supplier types.

3. Establishing Enhanced Medicare Provider Enrollment and Oversight Requirements

CMS proposes to tighten provider enrollment safeguards across Medicare, Medicaid, and CHIP by strengthening identity verification, accelerating reporting of changes in enrollment information, expanding grounds for enrollment denial and revocation, and adding a requirement that all providers and suppliers billing MA be enrolled in Original Medicare.

4. Stopping the Bleeding in the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Benefit

CMS proposes strengthening protections against fraudulent and high-pressure marketing by DMEPOS suppliers, including expanding the prohibition on unsolicited contact and ensuring transparency regarding domestic and foreign marketers. CMS also proposes reinforcing DMEPOS surety bond requirements to reduce Medicare Trust Fund losses when overpayments occur.

5. Crushing Marketplace Fraud

CMS proposes to greatly strengthen its authority to suspend or terminate agents, brokers, and web-brokers engaging in abusive conduct and to exclude or terminate agents, brokers, and web-brokers who pose an unacceptable risk of fraud, waste, and abuse, including those convicted of certain felonies or misdemeanors. Additionally, CMS proposes to increase transparency in enforcement actions following findings of agent, broker, and web-broker noncompliance with regulatory standards and enhance the security of Exchange systems and consumer information.

C. Summary of Costs and Benefits

Currently, the CMS Office of the Actuary (OACT) has not completed a quantitative score of the Federal budgetary or trust fund impacts of this proposed rule. OACT will score the rule and provide detailed financial impact projections in the final rule once policy parameters are finalized and public comments have been evaluated. We specifically request data and feedback from commenters regarding potential administrative, operational, and utilization impacts to assist OACT in developing its final estimates.

We estimate that, taken together, the quantified provisions of this proposed rule would

result in approximately $379 million in costs from 2027 to 2036. This estimate does not include the over $90 billion in transfers expected between the Federal government and State governments or private entities that may result from this proposed rule. CMS is seeking public comment on the accuracy of all cost and burden estimates included in this proposed rule.

II. Background

A. Authority

CMS' authority to issue program integrity rules flows primarily from the Social Security Act (the Act), as amended. The general authorities described here are in addition to the specific statutory authorities discussed with respect to each proposal. Sections 1102(a) and 1871(a)(1) of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

Section 1102(a) of the Act likewise provides general authority for the Secretary to prescribe regulations for the efficient administration of the Medicaid program and CHIP, while with respect to Medicaid, section 1902(a)(4) of the Act requires State plans to provide such methods of administration as are found by the Secretary to be necessary for the proper and efficient operation of the plan. .

For MA, the Secretary has authority under section 1856(b)(1) of the Act to adopt standards consistent with, and to carry out, Part C. The Secretary also has authority under section 1857(e)(1) to establish new MA contract terms and conditions where necessary and appropriate and not inconsistent with Part C. For Medicare Part D, section 1860D-12(b)(3)(D) provides that the Secretary's authority under section 1857(e) of the Act also applies to Part D.

For Medicaid, section 1902(a)(4) of the Act requires State plans to provide such methods of administration as are found by the Secretary to be necessary for the proper and efficient operation of the plan. For the Exchanges, section 1312(e) of the Affordable Care Act provides the Secretary with the authority to establish procedures under which a State may allow agents or brokers to (1) enroll qualified individuals and qualified employers in QHPs offered through

Exchanges, and (2) assist individuals in applying for advance payments of the premium tax credit (APTC) and cost sharing reductions (CSRs) for QHPs sold through an Exchange. Section 1321(a) of the Affordable Care Act directs the Secretary to issue regulations setting standards for meeting the applicable requirements of title I of the Affordable Care Act and the amendments made by that title. These standards concern the establishment and operation of Exchanges, the offering of qualified health plans through Exchanges, and such other requirements as the Secretary determines appropriate. Section 1313(a)(5) of the Affordable Care Act further directs the Secretary, with respect to activities carried out under title I, to provide for the efficient and nondiscriminatory administration of Exchange activities. It also directs the Secretary to implement any measure or procedure that the Secretary determines is appropriate to reduce fraud and abuse in the Administration of title I and has authority to implement under title I or another Act.

B. This Administration's Fight to Crush Health Care Fraud

Health care fraud, waste, and abuse is a pervasive issue that this Administration is tackling in an unprecedented fashion. For example, on March 16, 2026, President Trump issued Executive Order 14395, establishing the White House Task Force to Eliminate Fraud. Similarly, the HHS Secretary and the CMS Administrator have strongly demonstrated this Administration's dedication to crushing fraud in Medicare, Medicaid, the Children's Health Insurance Program (CHIP), the Basic Health Program (BHP), and the Marketplace. In June 2026, the Secretary and the Administrator joined the then-Acting Attorney General to announce the Justice Department's 2026 National Health Care Fraud Takedown, which resulted in charges against 455 defendants, including 90 doctors and other licensed medical professionals, for their alleged participation in health care fraud and opioid abuse schemes involving over $6.5 billion in false claims and

significant patient harm.[1] This is an example of the significant steps this Administration has taken to crush fraud since President Trump began his second term in January 2025.

During his first term, on October 3, 2019, President Trump issued Executive Order (EO) 13890 on Protecting and Improving Medicare for Our Nation's Seniors. This order directed CMS to annually promulgate regulatory or subregulatory changes to Medicare to enhance program integrity and promote payment accuracy and efficiency. CMS subsequently finalized a program integrity rule in 2023 (88 FR 80141) that required the disclosure of certain ownership, managerial, and other information regarding Medicare skilled nursing facilities (SNFs) and Medicaid nursing facilities (NFs). While CMS has issued many program integrity provisions in various rules or direction through subregulatory guidance, subsequent annual stand-alone program integrity rulemaking has not taken place.

Crushing fraud has been a central tenet of President Trump's second term, and undertaking rulemaking to address fraud vulnerabilities is a critical component of that fight. On February 27, 2026, CMS issued a Request for Information Related to Comprehensive Regulations to Uncover Suspicious Healthcare (CRUSH RFI) (91 FR 9803) to solicit interested parties' feedback on potential regulatory changes that might be included in this proposed rule, as well as other programmatic changes that could be implemented to make CMS more effective in crushing fraud.

Working tirelessly to crush waste, abuse, and fraudulent activities in our health care system remains a key CMS strategic priority. This includes leveraging new techniques, authorities, and policies that will enable CMS to continue shifting away from pay and chase methods to "stop and caught" approaches that allow us to swiftly remove bad actors from our programs which prevents dollars from going out the door towards fraud. We are issuing this Comprehensive Regulations to Uncover Suspicious Healthcare (CRUSH) proposed rule to solicit

[1] More information is available at https://www.justice.gov/criminal/criminal-fraud/2026-national-health-care-fraud-takedown.

interested parties' feedback on proposed regulatory changes to make CMS more effective in crushing fraud to protect taxpayer dollars and the Americans we serve.

C. Severability

CMS proposes that if any provision of the CRUSH proposed rule, if or when finalized, were held to be invalid or unenforceable—facially or as applied to any person, plaintiff, or circumstance—or stayed pending further judicial or agency action, such provision shall be severable from other provisions finalized, and from rules and regulations otherwise in effect, and not affect the remainder of provisions finalized. It was and continues to be our intent that, unless such provision shall be held to be utterly invalid or unenforceable, it be construed to give the provision maximum effect permitted by law including in the application of the provision to other persons not similarly situated or to other, dissimilar circumstances from those where the provision may be held to be invalid or unenforceable. The CRUSH proposed rule addresses numerous stand-alone proposals that can largely operate independently of one another. We seek public comments on these proposed approaches to severability and whether similar regulatory text should be added to additional proposals within this proposed rule.

D. Effective Dates

We propose that, unless we specify otherwise with respect to a particular a provision, the effective date would be 60 days after the publication of the CRUSH final rule. We request public comment on the feasibility of effective dates for each provision.

III. Medicaid and CHIP Program Integrity Proposals

Medicaid and CHIP are Federal-State partnerships, and these partnerships are central to the programs' success. CMS provides States with guidance; technical assistance, including tools and data; Federal matching funds for expenditures; and other resources to use in meeting statutory and regulatory requirements.

The Federal Government and each State jointly fund each State's Medicaid and CHIP programs. The Federal Government matches State Medicaid program expenditures at a specified percentage, called the Federal Medical Assistance Percentage (FMAP), which has a statutory minimum of 50 percent and maximum of 83 percent, though enhanced FMAP exceeding 83 percent is available for certain covered populations and services (for example, the 90 percent FMAP available for expenditures attributable to the Medicaid expansion population under section 1905(y) of the Act).[2] State CHIP expenditures are matched at an enhanced FMAP equal to the State's regular FMAP increased by 30 percent, but bounded by an upper limit as section 2105(b) of the Act provides that the CHIP enhanced FMAP may not exceed 85 percent.[3] Total Fiscal Year (FY) 2024 Medicaid and CHIP spending exceeded $962 billion, or over 18 percent of total national health expenditures.[4] The FY 2024 Federal share of Medicaid expenditures constituted 64.7 percent of total Medicaid spending[5]—in other words, nearly 2/3 of all Medicaid expenditures were Federal dollars, evidencing the need for heightened Federal scrutiny—while the FY 2024 Federal share of CHIP expenditures was $20 billion. Because Medicaid expenditures are a large and growing portion of Federal and State budgets, controlling inappropriate Medicaid spending has been, and continues to be, an Administration priority.

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[2] The FMAP is calculated annually, and Federal law specifies that the FMAP will be no lower than 50 percent and no higher than 83 percent. See section 1905(b) of the Act.

[3] The CHIP enhanced FMAP is calculated annually, and Federal law specifies that the enhanced FMAP available for CHIP expenditures may not exceed 85 percent. See section 2105(b) of the Act.

[4] *https://www.cms.gov/data-research/statistics-trends-and-reports/national-health-expenditure-data/nhe-fact-sheet.*

[5] CMS, Form CMS-64 Data as reported by States to the Medicaid Budget and Expenditure System, as of May 29, 2024, at *https://www.medicaid.gov/medicaid/financial-management/state-expenditure-reporting-for-medicaid-chip/expenditure-reports-mbescbes/index.html*.

States fund their share of their Medicaid programs and, within Federal and State guidelines, operate their individual programs through various activities, such as setting payment rates, paying claims, enrolling providers and beneficiaries, contracting with managed care plans,[6] improving service quality via quality improvement activities, claiming the Federal match of expenditures, and, critically, ensuring program integrity. States and CMS share responsibility for ensuring that State and Federal dollars are used to efficiently deliver quality health care services to eligible individuals and are not misused for fraud, waste, or abuse.

Effective program integrity controls are essential to ensure that Medicaid and CHIP funds are expended appropriately, providers meet applicable enrollment and screening requirements, and beneficiaries receive covered benefits and services in accordance with Federal and State requirements. Titles XIX and XXI of the Act contain provisions, several of which we describe here, establishing core State responsibilities related to provider oversight, fraud and abuse prevention, payment integrity, and proper administration of the Medicaid and CHIP programs. For example:

- Section 1902(a)(4) of the Act requires States to maintain such methods of administration as are found by the Secretary to be necessary for the proper and efficient operation of the State plan.
- Section 1902(a)(30)(A) of the Act requires States to provide methods and procedures necessary to safeguard against unnecessary utilization of care and services and to assure that payments are consistent with efficiency, economy, and quality of care, reinforcing States' responsibility to maintain effective payment integrity and program oversight.
- Section 1902(a)(27) of the Act requires States to enter into agreements with providers under which such providers agree to maintain and, upon request, furnish to the State agency or CMS records sufficient to support appropriate payment for services.

[6] For these purposes, managed care plans refers to MCOs, PAHPs, and PIHPs as defined at § 438.2.

- Section 1902(a)(37) of the Act, in addition to containing certain prompt payment requirements, requires States to maintain procedures for claims payment and prepayment and postpayment claims review, including review of appropriate data regarding recipients, providers, and services, to ensure proper and efficient payment of claims and management of the Medicaid program.

- Section 1902(a)(64) of the Act requires States to provide a mechanism to receive reports concerning alleged fraud, waste, and abuse, and compile data relating to such activities.

- Sections 1902(a)(77) and 2107(e)(1)(G) of the Act require States to comply with certain provider screening, oversight, and reporting requirements established by the Secretary in accordance with Section 1902(kk).

- Section 1936 of the Act establishes the Medicaid Integrity Program, which authorizes the HHS Secretary, acting through CMS, to enter into contracts with eligible third-party entities to carry out certain program integrity related activities. Pursuant to section 1936(b) of the Act, contractors may review the actions of individuals or entities providing Medicaid items or services; conduct audits of claims for payment for items or services furnished or administrative services rendered; identify overpayments to individuals or entities receiving Federal Medicaid funds; and provide education and training to providers, beneficiaries, managed care entities, and other stakeholders.

CMS has implemented many of the Medicaid and CHIP program integrity requirements established under Title XIX and XXI of the Act, including requirements implementing sections 1902(a)(38), 1902(a)(39), 1902(a)(42), 1902(a)(77), 1902(a)(78), 1936, 2107(e)(1)(C), 2107(e)(1)(D), and 2107(e)(1)(G) through regulations in 42 CFR part 455 and 42 CFR part 457, subpart I. These regulations establish Medicaid and CHIP program integrity requirements related to administering effective fraud detection and investigation programs, provider enrollment and screening, reporting, payment suspensions, provider terminations, recovery audit contractors, and related program integrity activities. Together, these statutory and regulatory

provisions reflect States' primary program integrity responsibilities to maintain effective systems to identify, prevent, detect, investigate, and address program integrity risks, including improper payments and fraud, waste, and abuse.

Relatedly, section 1904 of the Act authorizes the Secretary, after reasonable notice and opportunity for a hearing, to withhold Federal payment to a State after determining that a State plan no longer complies with the requirements of section 1902 of the Act, or that the State's administration of its State plan fails to comply substantially with those requirements. Accordingly, when CMS establishes regulatory requirements implementing provisions of section 1902 of the Act, States must comply with those requirements as part of their obligations under approved Medicaid State plans and may be subject to withholding of Federal matching funds should they fail to do so. States must also comply with applicable CHIP requirements, including provisions of title XIX incorporated through specific cross-references within Title XXI. Pursuant to section 2106(d)(2) of the Act, States may also be subject to withholding for substantial noncompliance with CHIP requirements.

Although existing statutory and regulatory requirements provide a strong foundation for Medicaid and CHIP program integrity when properly executed, CMS continues to identify vulnerabilities that limit States' and CMS' ability to effectively oversee Medicaid expenditures and address evolving fraud, waste, and abuse risks. Despite State and Federal efforts, Medicaid and CHIP improper payment rates have also remained persistently high. Improper payments are not always directly attributable to fraud, waste, or abuse, but they remain an important indicator of payment integrity challenges. For example, in FY 2025, eligibility errors specifically accounted for approximately 72 percent of all Medicaid and CHIP improper payments, resulting in an estimated $27 billion in projected Federal improper payments.[7] Recognizing that fraud schemes continually evolve in response to perceived opportunity, CMS is committed to

[7] 2025 Medicaid and CHIP Supplemental Improper Payment Data. *https://www.cms.gov/files/document/2025-medicaid-chip-supplemental-improper-payment-data.pdf.*

maintaining a sustained, long-term program integrity strategy that leverages advanced data analytics, innovative investigative tools and techniques, and close collaboration with State Medicaid Agencies and Federal, State, and local law enforcement partners to identify emerging threats and respond quickly as they arise.

CMS has recently intensified its efforts to crush fraud in Medicaid and CHIP nationwide. In the course of our efforts, we have identified instances of significant State noncompliance with program integrity requirements and have discerned new and emerging vulnerabilities in State program integrity operations and processes that put taxpayer dollars and beneficiaries at risk. These risks and vulnerabilities include inconsistent provider identification practices across Medicaid and CHIP systems and activities, limitations in the scope and detail of information currently reported to CMS regarding fraud and abuse investigations, and underutilization of electronic visit verification (EVV) information collected by States.

A. Overview of Proposed Policies

To strengthen Medicaid and CHIP program integrity and address the risks, vulnerabilities, and oversight challenges discussed above, we are proposing a series of regulatory changes designed to enhance provider oversight, strengthen payment integrity, improve data and reporting, support more effective fraud prevention and detection, and reinforce State accountability for meeting Federal program integrity requirements. Specifically, this rule proposes regulatory revisions at 42 CFR parts 431, 438, 447, 455, and 457 to strengthen Medicaid and CHIP program integrity oversight that would, unless otherwise stated, be effective 60 days after the publication of the final rule. We seek public comments on the following Medicaid and CHIP regulatory provisions, including the proposed effective dates:

- State Payment Suspension Updates and Reporting Requirements

++ Allowing States to Rely on CMS' or Other Federal Agencies' Credible Allegation of Fraud Determinations

++ Aligning Modifications to the Definition of Credible Allegation of Fraud

++ Maintaining a Medicaid and CHIP Payment Suspension During an Investigation

++ Verifying Good Cause Exceptions to Payment Suspension Requirements

++ Updating Payment Suspension Reporting Requirements

++ Applicability to CHIP

- Enhanced Electronic Visit Verification (EVV) Requirements

++ Use of EVV in Preliminary Investigations

++ EVV Data in Prepayment Claims Review

- Requiring National Provider Identifiers (NPIs) for Eligible Medicaid Provider Types
- Updating State Program Integrity Reporting Requirements
- Deregulation of the Medicaid Eligibility Quality Control (MEQC) Program
- Medicaid and CHIP Beneficiary Eligibility Audit Program
- Medicaid and CHIP Beneficiary Eligibility-Related Disallowances
- Payment Error Rate Measurement (PERM) Corrective Action Plans (CAPs)

++ State Submission of a Combined Medicaid and CHIP PERM CAP

++ Monitoring Implementation Progress and Evaluating the Effectiveness of Each Corrective Action

++ CMS Approval, Revision, Disapproval, and Implementation of State-Specific PERM CAPs

++ Semi-Annual Reporting Requirements for States with an Eligibility Improper Payment Rate Above 3 Percent for Consecutive Cycles

- Program Integrity Corrective Action Plans
- Medicaid Fee-For-Service Overpayment Reporting (60-day rule)
- Medicaid and CHIP Managed Care Oversight Policies

++ Medicaid and CHIP Eligibility Determination Requirements for Beneficiary Residency and Death

++ Overpayments for Ineligible Enrollees

++ Working Families Tax Cut (WFTC) Legislation (Pub. L. 119-21) and Capitation Overpayments

++ Request for information regarding how to protect Medicaid payments from improper deductions

CMS is also proposing a number of provisions related to Medicaid and CHIP provider enrollment, which are addressed in the larger discussion of provider enrollment in section V. of this proposed rule.

B. State Payment Suspension Updates and Reporting Requirements

Sections 1903(i)(2) and 2107(e)(1) of the Act relate to limitations on payment. In 2010, section 6402(h)(2) of the Affordable Care Act (ACA) amended the Act to provide that State payments to a Medicaid provider under investigation for a credible allegation of fraud are not eligible for Federal matching funds unless a good cause exception is met. Specifically, section 1903(i)(2)(C) of the Act provides that Federal payment shall not be made with respect to any amount expended for items or services furnished "by any individual or entity to whom the State has failed to suspend payments under the plan during any period when there is pending an investigation of a credible allegation of fraud against the individual or entity, *as determined by the State* [emphasis added] in accordance with regulations promulgated by the Secretary for purposes of section 1395y(o) [1862(o)] of this title and this subparagraph, unless the State determines in accordance with such regulations there is good cause not to suspend such payments[.]"

Our experience working on payment suspension matters has demonstrated to us that States often apply this important administrative tool inconsistently and frequently underutilize it. Although our existing regulations do establish certain "floor" requirements, we also recognize that States have varying standards and processes with their respective Medicaid Fraud Control Units (MFCUs) and other law enforcement partners, reflecting individual State policies on how payment suspensions are determined, applied, and maintained, as well as the applicability of

these requirements to CHIP. Some of this variation is a feature rather than a flaw: it allows States to develop best practices tailored to their own legal and administrative environments, which can then be shared with and adapted by other States. States' legal frameworks differ and we expect and respect that variation; however, we believe that all States, pursuant to their statutory and regulatory program integrity oversight obligations, should be identifying and investigating credible allegations of fraud, making referrals to law enforcement, and issuing payment suspensions when appropriate to prevent inappropriate payments. CMS expects all States to design and execute payment suspension strategies adapted to that State's fraud risk profile; both the strategies and the risk profile generally will be fluid as fraud is rarely static by location, point in time, or any other factor as fraudsters attempt to leverage and exploit vulnerabilities and points of weakness wherever they discern them. Especially given that the target is ever evolving and the administration of the programs varies based on State laws and policies within Federal contours, our goal is not attaining inter-State uniformity (indeed, among our objectives is fostering and promoting effective creativity), but instead for each State to work within its own legal landscape to maximize the effectiveness of payment suspensions as an administrative tool. States must utilize payment suspensions when appropriate and should draw on the experience of States that have implemented them successfully. States should also ensure they have the funding, staffing, data analytics, and other support needed to identify potential fraud, issue payment suspensions, and make appropriate referrals to law enforcement when potential fraud is uncovered.

At the same time, we are mindful that the consequences of a payment suspension on a provider can be significant and may adversely affect business operations well before any allegation is resolved, and that sometimes what originate as genuine credible allegations ultimately may not be indicative of fraud, waste, or abuse. We recognize that the threshold for establishing a credible allegation of fraud is intentionally lower than the evidentiary standards required for a formal fraud finding, as it is a temporary intervention to stop payments from going

out the door to a potentially fraudulent actor. A payment suspension imposed against a legitimate provider, even if only temporarily, can jeopardize that provider's viability and, in turn, disrupt beneficiary access to care, which might be most acutely felt in rural or underserved areas with few alternative providers. The current regulatory framework around good cause exceptions under § 455.23(e) and the additional proposals discussed in this section help ensure that payment suspensions remain a targeted, well-supported program integrity tool.

The following proposals outline how, consistent with statutory and regulatory authority, States may rely on other agencies for credible allegation of fraud determinations and for conducting investigations of such allegations, and the roles that CMS and law enforcement agencies play along with State Medicaid Agencies (SMAs) and CHIP agencies in determining when to issue and maintain payment suspensions.

Specifically, we propose that a State may choose to rely on credible allegation of fraud determination made by CMS or by other Federal agencies. These proposed changes would aim to streamline CMS', SMAs', and CHIP agencies' efforts to ensure Medicaid and CHIP integrity by allowing States to more quickly stop payments where a credible allegation of fraud exists. The regulatory proposals in this rule would be essential to help States quickly and correctly determine whether allegations of fraud are credible so that they could rapidly stop payments to individuals and entities and in connection with schemes under investigation for credible allegations of fraud, thus protecting the financial integrity of the Medicaid and CHIP programs and Federal taxpayer dollars.

1. Allowing States to Rely on CMS or Other Federal Agencies' Credible Allegation of Fraud Determinations

Under current regulations at § 455.23(a), an SMA must suspend all Medicaid payments to a provider after the agency determines there is a credible allegation of fraud against such provider for which an investigation is pending, unless the agency has good cause to not suspend payments or to suspend payment only in part. When an investigation leads to the initiation of a

payment suspension in whole or part, § 455.23(d) requires the SMA to also make a fraud referral to either the State's MFCU or, in States with no certified MFCU, to an appropriate law enforcement agency. If the MFCU, or law enforcement agency accepts the fraud referral for investigation, the payment suspension may continue until such time as the investigation and any associated enforcement proceedings are completed. There is a similarly defined path for a MFCU to refer a credible allegation of fraud for payment suspension to the SMA at § 1007.9(e). In CHIP, § 457.915 requires the CHIP agency to refer suspected fraud and abuse cases to the CHIP program integrity unit (if such a unit is established) and to appropriate law enforcement officials.

The current payment suspension regulatory framework has led to differing interpretations of what the statutory language "as determined by the State" in section 1903(i)(2)(C) of the Act requires of each State. This has led to variation as to what additional verification steps SMAs or CHIP agencies take when receiving referrals from outside sources, such as CMS or a Federal law enforcement agency, with States handling this process in different ways: some accept a referral as a credible allegation of fraud and immediately impose a payment suspension, while others independently determine the credibility of the allegation(s) before imposing a payment suspension. These divergent approaches create exploitable loopholes that bad actors may use to continue receiving Medicaid and CHIP payments and that make recoupment of improperly paid funds difficult. This is particularly problematic in those States that may not have the internal resources to independently investigate and establish a credible allegation of fraud in every instance. The longer payment suspensions are delayed, the greater the chance of payments continuing to flow to actors potentially defrauding the program.

To address these issues, we propose to add subparagraph § 455.23(a)(1)(i) to specify that a State may rely on a determination by CMS or any other Federal agency that a credible allegation of fraud exists for purposes of imposing a payment suspension and may rely on these agencies' investigations to satisfy the statutory requirement that there is pending an investigation

of a credible allegation of fraud against an individual or entity. This would include, for example, investigations conducted by CMS or another Federal agency, such as the U.S. Department of Justice, U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG), or the Department of Veterans Affairs. We believe this proposal would ease the burden on SMAs or CHIP agencies and reduce the time between when a credible allegation of fraud is referred and a payment suspension is implemented, translating into potential monetary savings for those States and for State and Federal taxpayers, as well as additional protections for those who could experience bodily or financial harm due to the possible underlying fraudulent activity. As stated under the proposed definition of credible allegation of fraud at § 455.2, a State may rely on such other agency determinations as a credible allegation of fraud unless the State has specific information indicating that reliance on the CMS or other agency determinations would be unreasonable under the circumstances. Thus, when accepting credible allegations of fraud from CMS or Federal agencies, SMAs and CHIP agencies may choose to adopt those agencies' determinations as their own.

2. Aligning Modifications to the Definition of Credible Allegation of Fraud

''Credible allegation of fraud'' is a statutory term as reflected in section 1903(i)(2)(C) of the Act. On February 2, 2011, CMS published a final rule with comment period (CMS-6028-FC) implementing the new Medicaid payment suspension requirements with an effective date of March 25, 2011. As part of that 2011 final rule, we declined to provide a more precise definition of the term, recognizing that different States may have different considerations in determining what may be a credible allegation of fraud. Instead, we specified at § 455.2 that a credible allegation of fraud may be an allegation verified by the State from any source, and that allegations are considered to be credible when they have an indicia of reliability and the State Medicaid agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis. However, as discussed in III(B)(1) of this proposed rule, although the statutory language says that a credible allegation of fraud should be "determined by the State," it

is left to each State in accordance with the Secretary's regulations to decide what that determination must entail. Currently, § 455.2 states that a credible allegation of fraud may arise from sources like fraud hotline tips, claims data mining, or patterns identified through audits and investigations, with credibility established through a State's review for indicia of reliability. In cases where CMS or another Federal agency has already made a credible allegation of fraud determination, requiring the State to independently re-verify that determination is duplicative, time consuming, and oftentimes not necessary. Moreover, the current definition does not explicitly address whether a State may rely on a credible allegation of fraud determination or investigation by CMS or another Federal agency. Without an explicit basis for relying on another agency's determination, we understand that some States duplicate investigative work, delay action, or forgo payment suspensions even when a credible referral already exists. Therefore, we are proposing several changes to the definition of "credible allegation of fraud" at 455.2 to make the Medicaid payment suspension process more efficient and to provide States with clarity as to when the imposition of a payment suspension is appropriate.

First, we propose to revise the definition to explicitly recognize determinations from CMS or another Federal agency as a potential source of a credible allegation of fraud. We are not including State agencies within this new provision; the existing referral pathway at § 1007.9(e) already addresses this category of State-level finding and is not amended by this rule. We believe this proposal would give States a clearer, faster path to act on well-supported referrals from CMS and other Federal agencies, while leaving the established MFCU referral process undisturbed and without need for a conforming amendment to the MFCU regulations at 42 CFR part 1007.

Second, we are proposing to reorganize the language of the credible allegation of fraud definition at § 455.2 to alleviate duplicative effort that we believe the phrase "which has been verified by the State" has caused. We propose that the definition instead provide that a credible allegation of fraud is an allegation that has indicia of reliability that may come from any source,

including but not limited to fraud hotline tips verified by further evidence, claims data mining, patterns identified through provider audits, civil false claims cases, and law enforcement investigations, or a determination by CMS or by another Federal agency that an allegation of fraud against a provider is credible.

Third, we propose at § 455.2 that an allegation has indicia of reliability through one of two pathways, depending on its source. For allegations arising from fraud hotline tips, claims data mining, or patterns identified through audits, civil false claims cases, and law enforcement investigations, an allegation has indicia of reliability when the State Medicaid agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis, consistent with the existing standard. For allegations based on a determination by CMS or another Federal agency, we propose that the State may adopt the referring agency's determination as its own without conducting an independent redetermination of credibility, unless the State has specific information indicating that reliance on the referring agency's determination would be unreasonable under the circumstances. We believe this presumption would appropriately reduce duplicative State effort while preserving a State's ability to decline reliance where it has a concrete basis to question the referring agency's determination.

We are not proposing to further define "indicia of reliability" in this rule. We have historically left this term undefined to preserve State flexibility to evaluate allegations according to the facts and circumstances presented, consistent with our approach in the 2011 final rule. We recognize, however, that the absence of further definition may create inconsistency across States in how allegations are evaluated, particularly as States begin to rely on determinations made by CMS or other Federal agencies under this proposal, where the referring agency's own application of "indicia of reliability" may not be transparent to the State relying on it. We solicit comments on the following questions:

- Should CMS further define "indicia of reliability" in regulation, and if so, what specific factors or criteria should that definition include?

- Would a non-exclusive list of factors, for example, the specificity of the allegation, the existence of corroborating documentation, the source's track record of reliability, or the existence of a related law enforcement referral provide useful guidance without unduly constraining State discretion on a case-by-case basis?
- Are there existing State-level frameworks for evaluating indicia of reliability that CMS should consider as models if it were to adopt further criteria in future rulemaking?
- What burden, if any, would a more detailed definition impose on States, and would that burden be offset by increased consistency?
- What additional internal controls, if any, States should be required to maintain to ensure that payment suspensions sustained under this provision are subject to adequate oversight, including the appropriate length of the law enforcement notice-and-objection period?

3. Maintaining a Medicaid and CHIP Payment Suspension During an Investigation

Currently, § 455.23(d)(4) directs that a payment suspension be discontinued if law enforcement declines the fraud referral, unless the SMA has alternative Federal or State authority to impose a suspension or make a referral to another law enforcement agency.

Payment suspensions are temporary measures, subject to defined procedural timeframes, and must be terminated upon specific triggering events specified at § 455.23(c) and (d), and through cross reference at § 457.935(b)(1). However, in practice CMS has observed that payment suspensions may be terminated prematurely, potentially causing at-risk funds to go unrecovered and taxpayer dollars to be lost. For instance, law enforcement agencies may decline State or Federal referrals for various reasons unrelated to the quality of the referral, such as personnel or other resource constraints or competing priorities. As the Medicaid payment suspension regulations currently stand, we did not directly account for the extent of resource constraints that law enforcement agencies may have in accepting a referral for investigation, nor the SMA resources it may take to refer a credible allegation of fraud to multiple agencies for an investigation to commence.

Therefore, we propose revising our regulations to specify that a SMA or CHIP agency may maintain a payment suspension when a credible allegation of fraud is present while the SMA or CHIP agency completes its own investigation, regardless of whether Federal or State law enforcement accepts the referral, if the SMA or CHIP agency documents in writing that the credible allegation of fraud remains under active investigation by the SMA or CHIP agency or by another State or Federal agency. We believe this proposal would appropriately preserve State flexibility to maintain suspensions in cases where the underlying credible allegation of fraud has not been resolved to ultimately determine whether payment should be made, or whether the provider's ability to bill the Medicaid or CHIP programs should be terminated. This would allow the SMA conducting the active investigation to act on its findings, such as by determining that a claim should be denied, that an overpayment exists and can therefore be recouped, or that a provider should be terminated.

However, we are mindful that Congress tied the payment suspension authority under sections 1903(i)(2)(C) and 2107(e)(1)(O) of the Act to the existence of a pending investigation of a credible allegation of fraud, and that the new authority provided by this regulation is not intended to function as an indefinite or open-ended tool. To ensure that a suspension maintained on this basis would remain pursuant to an active ongoing investigation, we are also proposing a requirement that the SMA or CHIP agency redetermine and document in writing, at least quarterly, whether the credible allegation of fraud continues to be under active investigation warranting continuation of the suspension. We propose that, where a Federal or State law enforcement agency accepted the referral and is conducting the investigation, prior to each quarterly redetermination taking effect, the SMA or CHIP agency notify the Federal or State law enforcement agency investigating the alleged fraud of its intent to continue or terminate the suspension, and afford that law enforcement agency the right to request that the payment suspension be kept (or terminated). Should the referring agency timely make such a request, the SMA or CHIP agency would consider the request in its decision to maintain or terminate the

payment suspension for that quarter. This approach would give the referring law enforcement agency a direct and time-limited mechanism to provide the least interference with a law enforcement investigation or prosecution. Where no law enforcement agency accepted the referral and the SMA or CHIP agency is conducting its own investigation, its quarterly written redetermination alone would satisfy this requirement. Furthermore, should an SMA or CHIP agency be unable to make a finding that there remains an active investigation at any such redetermination, we propose that it must immediately terminate the suspension. We believe this would ensure payment suspensions remain time-limited and subject to meaningful review while protecting Medicaid and CHIP dollars.

We note that this redetermination and termination authority would rest with the SMA and CHIP agency, and that their conclusions could sometimes diverge from those of the agency or agencies that referred the credible allegation of fraud in the first place. We have observed that defendants in Federal matters have, in some instances, cited a State's decision to decline to impose or its decision to subsequently terminate a payment suspension following a credible allegation of fraud referral as evidence that their conduct was believed to be permissible, potentially undermining an ongoing Federal investigation or prosecution involving substantially the same conduct. We encourage coordination between the SMA or/and CHIP agency, and the referring agency before a payment suspension maintained on the basis of that agency's referral is terminated. This would not give the referring agency veto power over the redetermination of a payment suspension at an SMA or CHIP agency, but, instead, would ensure the referring agency would have notice and a meaningful opportunity to share relevant information. For example, a law enforcement agency could share that a matter remains under active investigation and that terminating a payment suspension could adversely affect a related enforcement proceeding.

4. Verifying Good Cause Exceptions to Payment Suspension Requirements

Sections 455.23(e) and (f) currently specify bases for good cause exceptions to payment suspensions. In our experience, good cause exceptions are often invoked when a MFCU or other

law enforcement agency requests that a payment suspension not be imposed to prevent a provider from being made aware they are under investigation, which could jeopardize a civil or criminal case and possibly even the safety of the law enforcement officials conducting an investigation. Though that is a laudable and important goal, in recent years we have seen instances in which States seem to invoke good cause exceptions to avoid imposing payment suspensions for other reasons that do not meet the criteria outlined at § 455.23(e)(1). For example, CMS believes that some States may use the (e)(1) clause to avoid provider abrasion (that is, friction, frustration, and administrative stress) to retain providers within the State's Medicaid and/or CHIP network. Other States may want to avoid the administrative burden of implementing a payment suspension or the subsequent litigation risk inherent when payment is paused.

Data analysis bolsters our belief that States are over-relying on exercising § 455.23(e) and (f) payment suspension good cause exceptions. In CY 2025, for example, approximately 75 percent of credible allegation of fraud cases reported to CMS pursuant to State Medicaid payment suspension reporting requirements at § 455.23(g)(3) did not proceed to a payment suspension because an SMA invoked a good cause exception. Good cause exceptions have a legitimate place in payment suspension decision-making, but States should not use them as a blanket policy to reduce litigation risk or avoid their administrative responsibilities. Similarly, we encourage States to provide the most accurate good cause exception reasons and not solely rely – potentially inaccurately – on law enforcement exceptions. And while we expect variability among States, State-reported data revealed that several States had over 90 percent of their potential payment suspensions end with the exercise of a good cause exception, with some States exercising hundreds of good cause exceptions while instituting only a handful of payment suspensions. Such outlier scenarios potentially could be explained in very limited situations by events such as large law enforcement take-down operations in a State, but in no event should they, as we have seen, recur year-over-year. Instead, such patterns warrant our exercising

additional oversight to ensure good cause exceptions are applied in accordance with regulatory requirements.

To address this concern, we propose to require additional verifications as to whether the exercise of a good cause exception is appropriate. Specifically, we propose to modify § 455.23(e) to require States to evaluate, and document in writing, that the specific criteria for the exception invoked have been met in each instance. Further, we propose to modify § 455.23(e)(1) to require States to verify the reasons for good cause exceptions with law enforcement and send CMS the basis for each invocation of a good cause exception. Good cause exceptions must be invoked on a case-by-case basis, and SMAs and CHIP agencies must affirmatively verify with the relevant law enforcement agency that the exception is warranted for each individual case. A general or standing request from a law enforcement agency would be insufficient to satisfy this requirement.

We would not intend for this provision, if finalized as proposed, to serve as a categorical bar to good cause exceptions in all cases involving an active law enforcement investigation, nor would we expect SMAs or CHIP agencies to receive or ask for confidential, privileged, or legally protected information from law enforcement. But we would expect the case-specific merits for a good cause exception to be reviewed, confirmed or denied, and communicated by the MFCU or other law enforcement agency to the SMA or CHIP agency. At a minimum, the shared Federal and State goals—and, we believe, universally shared goals—should be to ensure that fraudulent providers are not inappropriately paid, while being circumspect and prudent with exercising authorities to best ensure legitimate providers are not inadvertently ensnared.

5. Updating Payment Suspension Reporting Requirements

Under our current regulations at § 455.23(g)(3), States are required to annually report to CMS summary information on the State's payment suspensions, including the nature of the suspected fraud, the basis for suspension, and the outcome of the suspension. In the 2011 regulation update of the Medicaid payment suspension regulations, we contemplated balancing

SMA burden and transparency as they determine whether to implement payment suspensions. At that time, we did not believe it would be necessary to review information on individual payment suspensions by a State with any regularity, and that an annual cadence would allow sufficient oversight over States' payment suspension activities. As discussed previously, however, we have observed over the past several years significant inconsistencies between States, and sometimes within each State over time, in payment suspension utilization. We understand and expect a degree of variability among States as this is a State-implemented program and States vary in program integrity risk profiles, but also expect a consistent level of due diligence in ensuring payments are made appropriately and that inappropriate payments are avoided. Important in that calculus, technological advancements over the past decade—including greatly improved data analytics yielding the ability to act on data in near-real time—have altered how businesses and governments run and make more regular reporting more feasible without commensurate burden.

We therefore propose to update § 455.23(g) reporting requirements to increase the reporting cadence from annual to quarterly, and to remove the word "summary" from the description of information to accommodate the increased detail that States would need to report to CMS. As we encourage States to appropriately utilize payment suspensions to halt potentially fraudulent payments, we strive for closer-to-real-time data and analytics on how those decisions are being made. As part of our oversight duties, if finalized as proposed, we would utilize this data to foster deeper discussions within SMAs and CHIP agencies on potential payment suspensions, and provide technical assistance and guidance, when requested or needed. We believe that more frequent reporting of payment suspension data would help States use this tool more effectively and obtain the necessary guidance from CMS.

We also believe that more frequent reporting would enable CMS to compile and analyze program-wide data on payment suspension activity within and across States more effectively. This information would be used to identify systemic trends and patterns in the use of payment

suspensions as a program integrity tool. Similar to how we use the data today, should our proposals be finalized as proposed, we would use this data to assess whether States are maintaining effective processes for evaluating credible allegations of fraud and making timely suspension decisions consistent with the proposed updates in §§ 455.23 and 457.935(b)(8), to inform CMS' State auditing activities, and to support aggregate reporting on Medicaid and CHIP program integrity outcomes. More frequent State reporting would also enable CMS to provide States more timely technical assistance to address any inconsistencies or other concerns.

We do not believe that more frequent reporting of this information would be substantially more burdensome to States than their current data sharing. For example, much of the data that States currently share annually with CMS already is shared quarterly, and perhaps even more frequently, between SMAs and their MFCUs through States' existing case tracking systems. In fact, § 1007.9(h) already requires MFCUs to send certain information regarding payment suspensions to SMAs, which the SMA must request quarterly per § 455.23(d)(3)(ii). Accordingly, we believe that any additional burden on States to supply such information to CMS would be nearly negligible. Similarly, while we expect that the shift to quarterly reporting would modestly increase CMS' administrative burden, we believe this increase would be negligible relative to our existing oversight infrastructure and be offset by the program integrity benefits of more timely reporting.

The proposed enhanced reporting requirements would not be intended to enable CMS to substitute its judgment for that of the State in individual cases, nor would they expand CMS' authority by permitting enforcement action based solely on disagreement with a State's individual suspension determination. Rather, CMS would use the reporting data to identify potential systemic deficiencies in a State's program integrity processes, which then could be examined through additional oversight activities, such as audits, and addressed through technical assistance or existing enforcement mechanisms, including deferral and disallowance of Federal Financial Participation (FFP) under §§ 430.40, 430.42, and 457.628(a), where appropriate.

We also propose a technical edit to update the title of § 455.23(g) to include reporting, to more accurately reflect all the subparagraphs.

6. Applicability to CHIP

Current regulations at § 438.608(a)(8) require that Medicaid managed care contracts include a provision for the suspension of payments to a network provider when the State determines there is a credible allegation of fraud, in accordance with § 455.23. Through the cross-reference at § 457.1285, we note that the requirements in § 455.23 are already applicable to CHIP managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs). Accordingly, any finalized provisions to § 455.23 would also apply to CHIP MCOs, PIHPs, and PAHPs.

However, we are concerned that the existing regulatory framework does not fully address payment suspensions in the CHIP fee-for-service (FFS) context. We therefore propose to update § 457.935(b) to include a cross-reference to § 455.23. This change would ensure that standalone CHIP programs would be held to the same standards as Medicaid MCOs, PIHPs, PAHPs, and FFS. We believe that including the cross-reference to § 455.23 would close potential program integrity gaps in the CHIP program and support stronger, more consistent program administration.

We seek comments on whether the proposed update to § 457.935(b) and current cross-references to § 455.23 provide sufficient clarity regarding the applicability of payment suspension requirements to CHIP. We also seek comments on whether additional regulatory text or cross-references would be needed to ensure that State CHIP agencies and their managed care partners have clear and actionable guidance on implementing these requirements.

C. Enhanced Electronic Visit Verification (EVV) Requirements

Personal care services (PCS) and home health care services (HHCS) that are delivered during an in-home visit are particularly vulnerable to fraud, waste, and abuse due to the limited direct oversight of services furnished in beneficiaries' homes. PCS are services that support

beneficiaries with Activities of Daily Living (ADLs) and Instrumental Activities of Daily Living (IADLs) and generally include, but are not limited to, meal preparation, grooming, dressing, and bathing.[8,9] PCS can be agency-based or self-directed. Under agency-based models, a personal care agency provides oversight, management, and supervision of a beneficiary's PCS. By contrast, self-directed PCS allows individuals, or their representatives, to exercise decision-making authority in the planning, accessing, managing, and purchasing of their PCS with available necessary supports and subject to applicable State oversight requirements, including, as applicable, the requirements specified at §§ 441.464 and 441.585(a).[10] Regardless of the PCS delivery model, the SMA is responsible for monitoring the quality of services.

PCS fraud and abuse schemes have been well documented in Federal oversight actions and prosecutions. Common PCS fraud and abuse schemes include personal care attendants (PCAs) billing for services not rendered, billing for excessive units, and billing for medically unnecessary services. In FY 2025, MFCUs reported 326 PCA fraud convictions, significantly higher than any other provider type.[11] PCS fraud and abuse leaves beneficiaries at risk for harm and neglect, and in severe cases has resulted in hospitalizations and deaths.

HHCS include, at a minimum, nursing services; home health aide services; and medical supplies, equipment, and appliances. At a State's option, HHCS can include physical therapy, occupational therapy, and speech pathology and audiology services. HHCS is a mandatory State plan benefit for specified individuals under section 1902(a)(10)(D) of the Act and is described in section 1905(a)(7) of the Act. Under specific circumstances, HHCS may also be provided under a waiver of the plan. HHCS are generally susceptible to many of the same fraud and abuse schemes as PCS, including but not limited to providers billing for services not rendered,

[8] § 440.167.
[9] The definition of PCS and the specific services covered vary depending on the applicable Medicaid authority.
[10] §§ 441.450 and 441.505.
[11] OEI-09-26-00140, Medicaid Fraud Control Units Annual Report: Fiscal Year 2025.

excessive units, or medically unnecessary services, and services provided by unqualified providers.[12] Like PCS, HHCS fraud and abuse can result in significant harm to beneficiaries.

In CY 2023, home and community-based services (HCBS) accounted for 63.8 percent of total Medicaid long-term services and supports (LTSS) expenditures.[13] Individuals who receive HCBS have significantly lower average expenditures than individuals who receive institutional care, but PCS and HHCS represent a substantial and growing share of HBCS spending.[14] Of the $145.9 billion in total HCBS expenditures in 2023, PCS spending totaled at least $36.1 billion and HHCS at least $6.9 billion.[15] When utilized and delivered appropriately, these services provide important supports that allow individuals to remain in home and community settings. However, they also present unique program integrity challenges because services are furnished in locations allowing for limited, if any, direct oversight.

EVV is a system used for in-home services, including PCS and HHCS, to electronically verify the service type, service recipient, date, location, provider, and service start and end time. Congress enacted EVV requirements in section 12006(a) of the 21st Century Cures Act, which added section 1903(l) of the Act, requiring States to implement an EVV system for Medicaid PCS and HHCS requiring an in-home visit by a provider. The requirements were established, in part, to reduce fraud, waste, and abuse in PCS and HHCS by increasing States' ability to validate that services are provided and monitor the accuracy of payments to providers.[16] States were

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[12] *See,* for example, United States Attorney's Office Northern District of Georgia, *Home Health Agency to Pay $4.2 Million to Settle False Claims Act Allegations,* https://www.justice.gov/usao-ndga/pr/home-health-agency-pay-42-million-settle-false-claims-act-allegations-0 (November 2021); United States Attorney's Office Southern District of Ohio, *Columbus Home Health Care Provider Sentences for Fraud,* https://www.justice.gov/usao-sdoh/pr/columbus-home-health-care-provider-sentenced-fraud (February 2019); *United States Attorney's Office Southern District of New York, Owner Of Home Health Agency Sentenced To 54 Months In Prison For Over $100 Million Health Care Fraud, https://www.justice.gov/usao-sdny/pr/owner-home-health-agency-sentenced-54-months-prison-over-100-million-health-care-fraud (*February 2023)

[13] *https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-rebalancing-brief-2023.pdf.*

[14] The average institutional services expenditure per user in 2023 was $54,462, compared to $17,298 for HCBS (*see* https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-rebalancing-brief-2023.pdf).

[15] The PCS spending estimate was calculated based on $18.6 billion for section 1915(j) services, $12.6 billion for section 1905(a) State plan PCS, and $4.9 billion for section 1915(k) services and the HHCS spending estimate was based on $6.9 billion for section 1905(a) State plan home health services (*see* https://www.medicaid.gov/medicaid/long-term-services-supports/downloads/ltss-users-expenditures-category-brief-2023.pdf).

[16] *See e.g.,* https://www.congress.gov/committee-report/114th-congress/house-report/667/1

generally required to have an EVV system in place for PCS by January 1, 2020, and for HHCS by January 1, 2023. States are subject to incremental FMAP reductions of up to 1 percent for failing to comply with these requirements by the applicable deadlines.[17]

States' EVV systems are required to electronically verify the following data elements for in-home PCS and HHCS visits: (1) the type of service performed; (2) the individual receiving the service; (3) the date of service; (4) the location of service delivery; (5) the individual providing the service; and (6) the time the service begins and ends.[18] Section 1903(l) of the Act does not require States to use a particular type of EVV system, affording States significant discretion in their EVV design and operation. There is also no statutory requirement for States to use global positioning system (GPS) data with respect to their EVV systems, and States are required only to collect the location of service delivery and the time the service begins and ends. States may, however, elect to collect additional information to mitigate fraud, waste, and abuse.[19]

Today, States routinely collect EVV data elements as part of program operations. However, as one commenter stated in response to the 2026 CRUSH RFI, there is currently a gap between the technical infrastructure — the EVV system — and its effective use for program integrity. The statute required that by not later than January 1, 2018, the Secretary collect and disseminate to SMAs best practices regarding the operation of EVV systems and the prevention of fraud with respect to the provision of PCS or HHCS.[20] State best practices for improved PCS and HHCS oversight include integrating EVV systems with other Medicaid systems, such as the State's Medicaid Management Information System (MMIS), Eligibility and Enrollment System (E&E), and Financial Management Systems (FMS), and conducting prepayment reviews of PCS and HHCS claims against EVV data.[21] By integrating EVV systems with claims processing

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[17] Section 1903(l)(1) of the Act.
[18] Section 1903(l)(5)(A) of the Act
[19] CMS, *Frequently Asked Questions: Section 12006 of the 21st Century Cures Act Electronic Visit Verification (EVV) Systems for Personal Care Services (PCS) and Home Health Care Services (HHCS),* https://www.medicaid.gov/federal-policy-guidance/downloads/faq051618.pdf.
[20] P.L. 114-255, § 12006(b)(1).
[21] CMCS Information Bulletin, *Electronic Visit Verification*, https://www.medicaid.gov/federal-policy-guidance/downloads/cib051618.pdf *(*May 2018).

systems, States can automatically compare claims with EVV data and prevent payments for PCS and HHCS claims that do not have matching EVV records. Additionally, some States have expanded EVV requirements to other in-home services beyond just PCS and HHCS.

Although CMS has published guidance on how States can use EVV to enhance quality monitoring and oversight of Medicaid services,[22,23] neither the statute nor current regulations establish EVV-specific requirements regarding the use of EVV records in claims review or program integrity activities.[24] In this proposed rule, we propose two related but distinct regulatory changes to require SMAs to use collected EVV data for program integrity and payment oversight. First, we propose to amend § 455.14 to require that SMAs incorporate a review of EVV records as part of preliminary investigations into potential Medicaid fraud or abuse involving in-home service providers subject to EVV requirements in a State. Accordingly, this requirement would apply to Medicaid providers furnishing services subject to Federal EVV requirements, as well as those subject to State requirements that extend EVV requirements to additional Medicaid services. Second, we propose to amend § 447.45(f)(1) to require that SMAs verify that billed Medicaid services are supported by EVV records, where applicable under Federal or State requirements, during prepayment claims review. Together, these proposals are intended to maximize States' existing EVV systems for improved program integrity oversight and better position States to crush Medicaid fraud and abuse within high-risk services.

1. Use of EVV Data in Preliminary Investigations

In accordance with § 455.14, when a SMA receives a complaint of potential Medicaid fraud or abuse from any source or identifies any questionable practices, it must conduct a preliminary investigation to determine whether the complaint warrants a full investigation.

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[22] CMS, L*everaging EVV to Enhance Quality Monitoring and Oversight in 1915(c) Waiver Programs (February 2020)*, https://www.medicaid.gov/medicaid/home-community-based-services/home-community-based-services-training-series

[23] *Electronic Visit Verification,* https://www.medicaid.gov/medicaid/home-community-based-services/home-community-based-services-guidance-additional-resources/electronic-visit-verification

[24] Statutory EVV requirements are not referenced in current Medicaid regulations.

States currently have broad flexibility in establishing procedures for preliminary investigations, including for those investigations conducted by managed care plans.[25]

When a State receives an allegation or complaint of potential Medicaid fraud, the State should review all allegations, facts, and evidence carefully to determine their validity; act on a case-by-case basis; and consider the totality of the facts and circumstances associated with any allegation.[26] In accordance with § 455.15, should a State believe that an incident of provider fraud or abuse has occurred based on the findings of a preliminary investigation, it is required to refer the case of suspected fraud or abuse to the State's MFCU for investigation, except in limited cases where no referral to the MFCU is required, in which case the State must conduct a full investigation or refer the case to the appropriate law enforcement agency.[27,28] As discussed previously, States must also suspend payments to a provider after the SMA determines that a credible allegation of fraud exists, unless good cause not to suspend or to suspend only in part exists.[29]

We propose to amend § 455.14 to require that SMAs incorporate a review of EVV records, where EVV use is required with respect to the underlying Medicaid service(s) in question under applicable Federal or State requirements, as part of preliminary investigations into potential Medicaid fraud or abuse. Specifically, we propose at new § 455.14(a)(1) that States be required to review and analyze the associated EVV records to attempt to verify the validity of an allegation of fraud or abuse or any identified questionable practice(s). This requirement would apply to any preliminary investigations of allegations of Medicaid fraud or

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[25] CMS, *Medicaid and CHIP Managed Care Program Integrity Toolkit*, https://www.cms.gov/files/document/managed-care-fraud-referral.pdf (June 2025).
26 CPI-CMCS Informational Bulletin, *Affordable Care Act Program Integrity Provisions - Guidance to States - Section 6402(h)(2)- Suspension of Medicaid Payments Based Upon Pending Investigations of Credible Allegations of Fraud,* https://www.medicaid.gov/federal-policy-guidance/downloads/payment-suspensions-info-bulletin-3-25-2011.pdf (March 2011).
[27] § 455.15(a).
[28] § 455.21(a).
[29] § 455.23.

abuse involving Medicaid services subject to EVV requirements under Federal or State requirements and the related providers suspected of such fraud or abuse.

The primary goal of this proposal would be to ensure that SMAs analyze and compare EVV records and claims to identify any discrepancies that warrant further investigation of providers subject to EVV requirements with fraud or abuse allegations or identified questionable practices. For example, during a preliminary investigation of an applicable provider, the SMA would be expected to review a sample of the provider's EVV records for the period under investigation to attempt to verify that services were delivered as billed, including for the appropriate duration and at the appropriate location, or determine if a full investigation pursuant to § 455.15 was warranted. This proposal seeks to enhance State identification and oversight of fraudulent and abusive activities by in-home service providers, including billing simultaneously for two beneficiaries in different locations, billing for improbably large volumes of services, and billing for services on the same day that would be geographically impossible to perform.[30,31,32]

We seek comments on this proposal, including on whether the proposed requirement should extend to investigations conducted by managed care plans under State managed care contracts and what operational steps States would need to take to integrate EVV record review into existing preliminary investigation procedures.

2. EVV Data in Prepayment Claims Review

Section 1902(a)(37)(B) of the Act requires States to have procedures for prepayment and post-payment claims review to ensure the proper and efficient payment of claims and management of the program. Regulations at 42 CFR 447.45 implement this statutory requirement. In accordance with § 447.45(f)(1), SMAs are currently required to conduct prepayment reviews for all claims consisting of: (1) verification of beneficiary and provider eligibility; (2) checks that services delivered are consistent with beneficiary characteristics and

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[30] *https://www.medicaid.gov/medicaid/downloads/evv-enhance-quality.pdf.*
[31] OIG-OR-2017-01.
[32] *https://www.justice.gov/criminal/media/1405081/dl?inline.*

circumstances; (3) verification that the claim does not duplicate or conflict with other claims; (4) verification that payment does not exceed State plan payment rates or limits; and (5) checks for third party liability.

We propose to amend § 447.45 by adding § 447.45(f)(1)(vi) to require that SMAs verify, during prepayment review, that billed in-home Medicaid services subject to Federal or State EVV requirements are supported by an EVV record, where applicable. Specifically, we propose that for home-based services subject to the requirements of section 1903(l) of the Act, and additional Medicaid services that the State independently subjects to EVV requirements, States verify during prepayment claims review that the following data elements are supported by an EVV record: (1) the type of service performed; (2) the individual receiving the service; (3) the date of service; (4) the location of service delivery; (5) the individual providing the service; and (6) the time the service begins and ends.

With this proposal to require that States use EVV data to verify applicable service claims during prepayment review prior to payment, we aim to encourage States to begin applying automated prepayment claims edits that take into consideration EVV data to stop inappropriate payments on the front-end, an approach we have long labeled "cost avoidance" and that is far more effective than "pay and chase." We believe this proposal, if finalized as proposed, would ensure States address Medicaid fraud in some of the highest risk services areas using technology, data analytics, and automated systems. We also believe this proposal is consistent with States' existing obligations under section 1902(a)(37) of the Act to maintain procedures for prepayment claims review to ensure the proper and efficient payment of claims. We also note that this proposal would complement our proposed amendment to § 455.14 described earlier in this proposed rule, as well as our proposal to require consistent use of NPIs for eligible Medicaid providers described in section E of this proposed rule. Together, these proposals, if finalized as proposed, would create a more integrated and effective framework for program integrity oversight of home-based services.

CMS would not condition claiming for FFP for EVV-required services on compliance with this provision. However, evidence of noncompliance (for example, as identified in a CMS audit) could cause CMS to reassess a State's compliance determination related to Section 1903(l) of the Act (as added by Section 12006 of the 21st Century Cures Act), which could result in FMAP reductions until compliance was achieved. Under section 1903(l) of the Act, States were required to attest that EVV use was required for all Medicaid-funded PCS (for calendar quarters beginning in 2020) and HHCS (for calendar quarters beginning in 2023) or otherwise be subject to FMAP reductions up to 1 percent. Although section 1903(l) does not specifically require EVV as a prepayment condition, substantive evidence that a State's claims for EVV-required services were not supported by EVV records could indicate that the State was not sufficiently requiring EVV use for those services. Similarly, CMS could take compliance with this provision into account during the certification process for States requesting enhanced FFP for their EVV systems.[33]

We seek comments on this proposal, including on the operational feasibility of requiring EVV-based prepayment review for all Medicaid service claims subject to Federal or State EVV requirements, whether States would need a transition period before this requirement could take effect, and whether there could be circumstances in which an EVV record might not be available for a legitimate claim, and how States should handle such situations.

Additionally, we acknowledge that, because the prepayment and post-payment review requirements in § 447.45 do not apply to risk-based managed care plans (as there is no cross-reference to § 447.45(f) in § 447.46(c)), the proposals in this section would only apply to Medicaid FFS; however, we are considering extending this proposed requirement to Medicaid managed care as a part of this rulemaking and explicitly seek comments on this approach. Applying this proposed requirement to managed care would necessarily require first extending

[33] https://cmsgov.github.io/CMCS-DSG-DSS-Certification/Outcomes%20and%20Metrics/Electronic%20Visit%20Verification%20(EVV)/

the established prepayment and post-payment claims review requirements at § 447.45(f) to MCOs, PIHPs, and PAHPs. We believe that many plans already use prepayment and post-payment processes as a part of their program integrity framework, and we request public comment on the feasibility of applying prepayment and post-payment claims review, and in turn the EVV prepayment requirements, to risk-based managed care.

D. Requiring National Provider Identifiers (NPIs) for Eligible Medicaid and CHIP Provider Types

We propose to revise § 455.440 to establish broader requirements for States to collect, maintain, and use NPIs for eligible Medicaid and CHIP providers. We would retain, without substantive change, the existing requirement that claims for ordered or referred items and services contain the NPI of the physician or other professional who ordered or referred those items or services, and designate that requirement as paragraph (a). We propose to add paragraphs (b) through (d) to establish the broader NPI requirements described below. Under § 457.990(b), the requirements of part 455, subpart E, including § 455.440, apply to separate CHIP programs in the same manner as they apply to Medicaid. Accordingly, the proposed requirements would apply to separate CHIP programs through that existing cross-reference.

Effective provider identification is foundational to Medicaid and CHIP provider enrollment, screening, ownership, and disclosure review; claims oversight; managed care oversight; auditing; reporting; and other program integrity activities. The Department adopted the NPI as the standard unique health care provider identifier under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification provisions.[34] The NPI final rule (69 FR 3434) established the NPI as the standard unique identifier for health care providers and recognized that NPIs may be used for numerous provider identification purposes, including provider enrollment systems, fraud and abuse files and other program

34 45 CFR part 162, subpart D; HIPAA Administrative Simplification: Standard Unique Health Identifier for Health Care Providers, 69 FR 3434 (January 23, 2004).

integrity functions, and debt collection activities. The NPI was developed in part to address longstanding challenges associated with multiple provider identifiers. Prior to implementation of the NPI, providers often maintained different identifiers across health plans, programs, and administrative systems. The NPI established a nationally standardized identifier capable of supporting provider identification across operational and administrative functions.

Although NPIs are widely used throughout the health care system, CMS has observed significant variation in how provider identifiers are collected, maintained, and used within Medicaid programs, and has determined that broader and more consistent use of NPIs would strengthen States' ability to carry out their program integrity responsibilities. Under current Medicaid program requirements, however, States are not required to collect, maintain, or use NPIs consistently across all Medicaid systems and activities. As such, the same provider may be identified differently across a State's provider enrollment system, claims processing system, managed care oversight system, and program integrity system, which can lead to difficulties identifying providers in Federal reporting systems, such as the Data Exchange System (DEX). For example, a PCA who is not required to have an NPI may be assigned different State or system-specific identifiers across these systems; may be identified individually in one system but associated with an employing agency or fiscal intermediary in another; or may have variations in recorded information such as name, address, or provider type. These State inconsistencies create meaningful vulnerabilities in program oversight on both State and Federal levels. For example, providers operating across State lines may maintain multiple identifiers, making it more difficult to detect billing for overlapping shifts or other suspicious billing patterns across programs. Reliable provider identification is particularly important for providers furnishing services in home- and community-based settings, where direct oversight is limited and fraud risk is elevated.[35]

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35 CMS has previously clarified that Medicaid PCAs who qualify as health care providers under applicable Federal regulations may obtain NPIs, and that a unique numeric identifier, such as the NPI, is an efficient mechanism for electronically recording which individual furnished services to a specific beneficiary. Medicaid and CHIP FAQs:

These inconsistencies also reduce the usefulness of data reported to CMS under § 455.17, limit cross-State matching efforts, and complicate CMS' ability to conduct national trend analysis and identify emerging fraud schemes. Program integrity professionals often use proactive data models to identify suspicious billing patterns, such as payment outliers, or to identify potential networks of fraudulent providers, but the accuracy of these analytics depends on consistent use of uniform metrics, including NPIs, and the absence of standardized provider identifiers limits CMS' and States' ability to effectively conduct this kind of analysis. Consistent use of NPIs enables States and national data aggregators, such as the Healthcare Fraud Prevention Partnership, to more accurately identify suspect providers across payors, programs, and States. Requiring consistent NPI use may also simplify States' screening of exclusion and termination lists maintained by the HHS-OIG and other oversight entities, improving States' ability to identify and act on adverse provider actions across programs. Additionally, requiring States to collect and use NPIs for all Medicaid and CHIP providers eligible to obtain an NPI would strengthen oversight of many high-risk service areas and better position States to use EVV data effectively for program integrity purposes, as discussed further in section C of this proposed rule. We believe these policies are necessary to strengthen program integrity, improve data quality and information sharing, support more effective data analytics, and promote the proper and efficient administration of State Medicaid programs under section 1902(a)(4) of the Act. Applying the proposed NPI requirements to CHIP through § 457.990(b) would similarly support consistent provider identification and program integrity oversight in separate CHIP programs.

Accordingly, we propose at § 455.440(b) through (d) to require States to collect, maintain, and use NPIs for all Medicaid and CHIP providers that are eligible to obtain an NPI under applicable Federal law and regulations. Specifically, under this proposal, States would be required to collect, maintain, and use NPIs as part of Medicaid and CHIP provider enrollment, revalidation, claims processing, managed care oversight, program integrity, and reporting

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Allowability of Using National Provider Identifiers (NPIs) for Medicaid Personal Care Attendants (PCAs).

activities for all providers eligible to obtain an NPI as a covered health care provider under 45 CFR part 162. As it relates to managed care oversight under 42 CFR part 438, we believe that States should ensure MCPs include applicable NPIs in any data, reporting, or other elements needed for effective oversight of MCPs. Such consistency in NPI use across Medicaid fee-for-service, managed care, and CHIP programs would allow States and CMS to conduct comprehensive and consistent data analytics and oversight.

We recognize that not all providers enrolled in Medicaid or CHIP are eligible to obtain NPIs under applicable Federal law. Eligibility for NPI enumeration is governed by the HIPAA Administrative Simplification regulations, including the definition of "health care provider" at 45 CFR 160.103, as discussed in the NPI final rule (69 FR 3436 through 3441, and 3466). Our proposal would not modify those existing eligibility requirements. Accordingly, some individuals or entities furnishing Medicaid and CHIP services, including certain PCAs and other non-traditional provider types, may not qualify as covered health care providers under 45 CFR 160.103 and therefore, may not be eligible for NPI enumeration. For those entities and individuals, we continue to strongly encourage as a best practice that States maintain another unique identifier capable of supporting enrollment, screening, claims oversight, reporting, and program integrity activities. Regardless of NPI eligibility, CMS encourages States to maintain a unique identifier for every provider enrolled in their Medicaid program, and we may consider proposing a formal requirement in future rulemaking as we gather more information through this comment process.

We seek comments on these proposals, including on the operational feasibility of requiring consistent NPI use across all Medicaid and CHIP systems, the timeframe States would need to come into compliance, and any challenges States anticipate in implementing these requirements for specific provider types. In the absence of comprehensive national data identifying the number and characteristics of all providers that would be newly affected by these proposed requirements, we use PCAs as a reasonable proxy when estimating the potential

administrative and financial burden associated with obtaining an NPI and completing related provider enrollment activities. We also seek comment on whether PCAs are an appropriate proxy for these estimates.

E. Updating State Program Integrity Reporting Requirements

States currently report certain provider fraud and abuse information to CMS pursuant to § 455.17. These reporting requirements were established in a January 27, 1983 final rule (48 FR 3742) (hereinafter referred to as the January 1983 final rule) and designed primarily to capture basic information regarding provider fraud and abuse investigations. The authority to collect this information expired in 1986, and following that expiration, CMS did not collect the information from States under § 455.17. While these reporting requirements may have provided useful information to CMS and its oversight partners, they have not been updated to reflect significant changes in the law and regulatory landscape. They were, for example, developed decades before the 2006 enactment of the Medicaid Integrity Program at section 1936 of the Act, which significantly bolstered our development of nationwide Medicaid program integrity efforts, and before the widespread use of modern data analytics, cross-State information sharing, managed care program integrity activities, and many current fraud detection techniques.

Under the existing requirements at § 455.17(a), States are required to report to CMS the number of fraud and abuse complaints that warrant preliminary investigation. Under § 455.17(b), for each case of suspected provider fraud and abuse that warrants a full investigation, States are required to report the: (1) provider's name and number; (2) source of the complaint; (3) type of provider; (4) nature of the complaint; (5) approximate range of dollars involved; and (6) legal and administrative disposition of the case, including actions taken by law enforcement. Consistent with the January 1983 final rule, these reporting requirements have applied only to suspected provider fraud and abuse cases and have not extended to suspected beneficiary fraud cases.

These requirements have provided a foundation for Medicaid program integrity reporting for over 40 years, but CMS has determined that they no longer provide the level of detail necessary to support effective national oversight or provide CMS with sufficient information to hold States accountable for lacking program integrity operations. Specifically, existing reporting requirements do not consistently provide information necessary to support national trend analysis, identify emerging fraud schemes, evaluate investigative outcomes, or coordinate oversight activities among Federal and State partners. CMS, SMAs, MFCUs, Unified Program Integrity Contractors, managed care plans, and law enforcement entities routinely coordinate activities involving provider investigations and administrative actions, and more detailed and standardized reporting would meaningfully strengthen those efforts. Modern data analytic systems also allow us to rapidly ingest and synthesize vast amounts of data and information, and in near-real time convert that to actionable intelligence.

We have also identified specific data gaps in existing reporting that limit its usefulness for program integrity purposes. The current language at § 455.17 only requires States to report on the six data elements enumerated earlier in this proposed rule. The prior reporting requirement did not consistently capture provider identifiers in a standardized format, limiting CMS' ability to cross-reference reported cases against other data sources or match investigation records across States and programs. It also does not capture the estimated or final overpayment amounts associated with investigated cases, limiting CMS' ability to evaluate the financial impact of fraud and abuse activity or assess the effectiveness of State investigative efforts. Finally, the prior reporting requirement does not capture administrative actions taken by SMAs (such as provider terminations, payment suspensions, and overpayment recovery actions) separately from law enforcement dispositions, limiting CMS' visibility into the full range of program integrity actions States are taking in response to identified fraud and abuse.

To address these issues, we propose to revise § 455.17 to modernize Medicaid fraud and abuse reporting requirements and improve the usefulness of information reported to CMS.

Consistent with the existing scope of § 455.17, these proposed revisions would apply only to suspected provider fraud and abuse cases and would not extend reporting requirements to beneficiary fraud and abuse cases. Specifically, we propose to amend § 455.17(b) to require States to report the following data elements for cases of suspected provider fraud and abuse that warranted a full investigation, the: (1) provider's name; (2) provider's NPI or Medicaid provider identification number if the provider is ineligible to receive an NPI under applicable Federal law; (3) provider's Employer Identification Number or Taxpayer Identification Number (EIN/TIN), if available; (4) State in which the investigation is being conducted; (5) source of the complaint; (6) type of provider; (7) type of service involved; (8) nature of the complaint; (9) payor (for example, Medicaid fee-for-service or managed care); (10) relevant claim dates; (11) approximate time period covered by the investigation; (12) estimated overpayment amount; (13) final over payment amount where a final determination has been made; (14) investigation status; and (15) legal and administrative disposition of the case, including actions taken by law enforcement and administrative actions taken by the State Medicaid agency, such as provider termination, payment suspension (including good cause exceptions identified under § 455.23), and overpayment recovery status.

We also propose to renumber the existing § 455.17(b)(6) and expand is scope to include additional reporting options to expand the reporting options for include the disposition of the case to include administrative actions taken by the SMA, including provider termination, payment suspension (including good cause exceptions identified under § 455.23), and overpayment recovery status, in addition to the existing requirement to report actions taken by law enforcement.

We believe these changes would meaningfully improve CMS' nationwide visibility into program integrity activities, facilitate trend analysis, improve coordination among Federal and State oversight entities, and support evaluation of program integrity outcomes. We also believe these enhanced reporting requirements would strengthen States' ability to meet their

responsibilities relating to fraud and abuse reporting, oversight, and data analysis under section 1902(a)(64) of the Act. We also specifically seek comment on the operational feasibility of the proposed data elements, whether additional data elements should be included, and the timeframe States would need to come into compliance with the revised reporting requirements.

F. Deregulation of the Medicaid Eligibility Quality Control (MEQC) Program

On July 5, 2017, we published a final regulation entitled Changes to the Payment Error Rate Measurement (PERM) and Medicaid Eligibility Quality Control (MEQC) Programs (82 FR 31158). This final rule updated the PERM and MEQC programs based on the changes to Medicaid and CHIP eligibility requirements under the Affordable Care Act. Those regulations restructured the MEQC program into an ongoing series of pilots that States are required to conduct during the two off years between triennial PERM review years, aiming to reduce repeat errors during the next PERM review.[36] The restructured MEQC program was designed to complement the PERM program by giving States[37] an opportunity to improve the quality, accuracy, and timeliness of their Medicaid and CHIP eligibility determinations before their next PERM measurement, helping ensure they make accurate and timely eligibility determinations so that Medicaid and CHIP services are appropriately provided to eligible individuals. States can use the MEQC pilots to address error-prone areas identified during past PERM reviews and prepare for upcoming triennial PERM reviews, but, importantly, MEQC requires States to conduct reviews of negative Medicaid and CHIP eligibility determinations (individuals denied or terminated from Medicaid and CHIP) whereas PERM reviews only paid claims related to active cases (individuals eligible for and enrolled in Medicaid and CHIP). During the States' MEQC review year, States are required to review at least 400 active cases and a minimum of 200 Medicaid and 200 CHIP negative cases, with flexibility to focus on vulnerable or error-prone areas. This approach allows States to assess the complete enrollment process to determine if any terminations or denials were improper.

CMS oversees the MEQC program and ensures that States implement its requirements specified at § 431.800 through § 431.820. Following the conclusion of the pilot, States must

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[36] Under the PERM requirements at 42 CFR 431 Subpart Q, the PERM program annually measures the national Medicaid and CHIP improper payment rates using a 17-State 3-year rotation process. The national Medicaid improper payment rate includes findings from the most recent three cycle measurements so that all States are captured in one rate. As such, each State is reviewed once every 3 years, and the year in which a State is measured is known as its ''PERM year." A State is not required to conduct a MEQC pilot during its PERM year. When a State is not under PERM review (that is, in the 2-year interval between a State's PERM review cycles), the State is

submit to CMS detailed case-level reports on the case review findings and a CAP to address all the identified errors and deficiencies. The MEQC pilots do not generate an eligibility improper payment rate, but instead allow States to implement corrective actions before their next PERM eligibility improper payment rate measurement.[38] In addition, under current regulations, participation in and compliance with the MEQC program is required for a State to qualify for a good faith waiver of the disallowance should their eligibility improper payment error rate exceed the 3 percent statutory threshold.[39]

Notwithstanding our well-meaning efforts around MEQC program design and the benefits we aimed for States to achieve, our longtime experience with it has demonstrated that its significant CMS and State administrative burden has substantially outweighed its benefits. MEQC pilots have not effectively reduced PERM eligibility improper payment rates. For example, overall Medicaid and CHIP eligibility improper payment rates increased during review years 2019 through 2021 (8.36 percent to 16.62 percent, and 23.53 percent to 28.71 percent, respectively).[40]

The MEQC program is largely a State-led audit process, with States developing the case sampling and review methodologies, and determining, based on their own interpretations of Federal regulations and State policy, whether findings represent errors or technical deficiencies. That system has not enabled CMS to render significant oversight, and we have limited ability to require States to target known areas of risk and ensure meaningful corrective action. More specifically, we currently have limited authority to direct MEQC case reviews to proactively target emerging or known high-risk areas in a State; ensure consistent application of Federal standards across State case reviews; or ensure that States properly calculate, quantify, and report

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required to conduct MEQC activities, including one (1) 12-month MEQC pilot. We refer to this 2-year interval between PERM review periods as PERM "off-years."

[37] States defined as the 50 States, District of Columbia, and the Commonwealth of Puerto Rico; *https://www.medicaid.gov/medicaid/eligibility/downloads/meqc-updated-phase1-guidance-05132021.pdf.*

[38] For more information on the traditional MEQC program, *see generally,* 82 FR 31158.

[39] § 431.1010 outlines the Secretary's authority to issue disallowances for certain eligibility-related overpayments.

[40] *https://www.cms.gov/data-research/monitoring-programs/improper-payment-measurement-programs/payment-error-rate-measurement-perm/perm-error-rate-findings-and-reports.*

confirmed overpayments, including estimated FFP. Furthermore, under § 431.812(b)(3)(ii), we may direct a State to perform focused reviews only if the State's PERM eligibility improper payment rate exceeds the 3 percent national standard for two consecutive PERM cycles.

MEQC regulations require States to provide updates on corrective actions reported for the previous MEQC pilot, but the current MEQC program design makes comprehensive oversight of those CAPs challenging. For example, should a CAP not adequately address a previously identified error, we may not become aware of this until the next MEQC or triennial PERM cycle. Also, the MEQC and PERM programs have often proved to be largely duplicative in both the errors identified and the associated corrective actions. States often rely on the same staff to administer their MEQC program and cooperate with CMS contractors and staff during PERM reviews. The labor-intensive nature of addressing findings may require States to temporarily pause MEQC work to appeal/dispute PERM findings. This overlap increases administrative burden, particularly for States balancing limited resources and staff. In fact, States have reported that limited State funding and competing priorities have, in some cases, resulted in State eligibility system errors remaining unaddressed in subsequent MEQC and PERM reviews. Additionally, the PERM and MEQC measurement cycles do not effectively align to enable States to test PERM CAP mitigation interventions during MEQC reviews before the State's next PERM review.

Although the MEQC payment review process allows us the limited ability to recover FFP associated with certain overpayments arising out of erroneous eligibility determinations, such recoveries have been minimal. Consistent with § 431.812, our May 13, 2021 MEQC guidance specifies that States must report and return the Federal share of any self-identified overpayment(s) that occurred for paid claims with dates of service in the first 3 months after the effective date of eligibility that was triggered by an identified erroneous eligibility determination.[41] This State-driven process has led to limited overpayment recoveries from the

[41] *https://www.medicaid.gov/medicaid/eligibility/downloads/meqc-updated-phase1-guidance-05132021.pdf.*

MEQC pilots and a lack of effective oversight of the accuracy of States' self-reported overpayment amounts. Also, section 1903(u) of the Act sets a 3 percent allowable threshold for program-wide eligibility improper payment rates in any full fiscal year after 1983, and specifies that the Secretary is generally required to disallow payments to States with respect to the amount of erroneous excess payments above that threshold.[42] However, the Secretary has the authority to waive all or part of the disallowance of FFP should a State be unable to reach the 3 percent allowable threshold despite a good faith effort to reduce its eligibility improper payment rate. As stated above, under current regulations, participation in and compliance with the MEQC program is required for a State to qualify for a good faith waiver of the disallowance should their eligibility improper payment error rate exceed this 3 percent statutory threshold. This is a relatively low bar that allows States to easily avoid disallowances, even if their improper payment rate for eligibility errors is well above 3 percent. In fact, to date, we have granted good faith waivers from disallowances to every State that had an eligibility improper payment rate measured through the PERM program above the 3 percent allowable threshold.

Given the program limitations and persistent beneficiary eligibility errors described previously, we do not believe that proposing changes to the MEQC regulations would effectively strengthen our beneficiary eligibility oversight efforts. Instead, to address inefficiencies and reduce burden—and as a part of an enhanced strategy to promote more robust and effective program integrity oversight of Medicaid and CHIP beneficiary eligibility determinations—we propose to deregulate (that is, eliminate) the MEQC program at §§ 431.800 through 431.820 and, separately, to codify a new audit and disallowance strategy that we describe in sections III.G. and III.H. of this proposed rule. We propose to phase out the MEQC program over the course of 3 years following publication of the final rule. We will ensure there is no overlap between PERM and beneficiary eligibility audits for purposes of disallowances in a given year. We propose that

[42] Section 1903(u) of the Act does not apply to Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, or American Samoa.

the section 1903(u) disallowance authority would be applicable under the eligibility audit program instead of PERM, starting on July 1, 2027, before the next PERM cycle begins (RY 2029). The MEQC payment review process for over and underpayments will continue to operate under current regulations § 431.812 (e) until the program is phased out for each review cycle. For the MEQC program, current good faith effort regulatory criteria would be applied until the proposed § 455.804 becomes effective. At that point MEQC participation would no longer be a factor in States receiving a good faith effort waiver from disallowance. Starting July 1, 2027, PERM CAPs would remain part of the good faith waiver criteria (under new 455.804) but disallowances would no longer by determined by the PERM program. Processes related to the other components of PERM (managed care and fee-for-service) would remain unchanged. The good faith waiver criteria in proposed § 455.804 would be applicable for disallowances arising under proposed § 455.802 once the MEQC program is phased out, should our proposals be finalized as proposed. Because the MEQC program would no longer exist, MEQC participation could no longer be included as a criterion for determining a good faith waiver.

We propose to deregulate the MEQC program in phases to ensure States would have adequate transition time to unwind from a longstanding program. Should this proposal be finalized, we anticipate that we would release additional information through sub-regulatory guidance that would provide further operational details for each 17-State MEQC cycle. We propose to remove §§ 431.800 through 431.820 from the Code of Federal Regulations at the conclusion of the phase-out period, with an effective end date 3 years after the publication of the final rule is published. We seek comment on this proposal to deregulate the MEQC program.

G. Medicaid and CHIP Beneficiary Eligibility Audit Program

Beneficiary eligibility determination errors account for a significant percentage of Medicaid and CHIP improper payments. In FY 2025, these errors represented approximately 72 percent and 73 percent of Medicaid and CHIP improper payments, respectively, totaling an estimated $27 billion in projected Federal Medicaid improper payments and $1 billion in

projected CHIP improper payments.[43] One way that we currently address this challenge is through beneficiary eligibility audits, which are CMS audits of States' Medicaid and CHIP beneficiary eligibility determinations. These audits, which are separate from PERM eligibility reviews and MEQC pilots, provide us with enhanced oversight of States' eligibility determination processes and enable us to offer recommendations to prospectively improve the accuracy of States' eligibility determinations.

We conducted beneficiary eligibility audits across seven States from 2019 to 2022 to verify States' compliance with Federal and State eligibility requirements.[44] The primary objective was identifying whether the selected States correctly determined Medicaid or CHIP eligibility at the point of application or renewal and claimed the appropriate FMAP. We reviewed States' eligibility determinations for sampled beneficiaries to assess compliance with Medicaid eligibility requirements under 42 CFR part 435 and where applicable, CHIP eligibility requirements under 42 CFR part 457.[45] Those Medicaid and CHIP beneficiary eligibility audits revealed significant State errors leading to frequent inaccurate beneficiary eligibility determinations and identified substantial estimated potential overpayments. Because statutory and regulatory provisions limited our ability to recover FFP associated with eligibility-related overpayments,[46] the audit focus was providing States with best practices to improve eligibility determination processes. For example, across the seven States audited, we identified $2.9 million in sampled overpayments associated with ineligible beneficiaries, which could be extrapolated to $231 million in potential overpayments for the universe sampled; as discussed in

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[43] 2025 Medicaid and CHIP Supplemental Improper Payment Data. *https://www.cms.gov/files/document/2025-medicaid-chip-supplemental-improper-payment-data.pdf*.

[44] The eligibility audit reports are available on *CMS.gov* on the *Reports & Guidance* webpage at: *https://www.cms.gov/medicare/medicaid-coordination/center-program-integrity/reports-guidance.* Eligibility audits were previously conducted in New York, Kentucky, Louisiana, Pennsylvania, Connecticut, Kansas, and Missouri. The audit target population varied across States, with three audits focusing on the Medicaid adult expansion population and four audits covering beneficiaries enrolled in the general Medicaid population, Medicaid adult expansion population, and CHIP.

[45] Individual cases were selected from a stratified random sample of beneficiaries whose eligibility was determined or redetermined during the audit period.

[46] The PERM program is used to implement section 1903(u) of the Act, and therefore, is currently the only mechanism for CMS to recover identified eligibility-related overpayments in Medicaid.

greater detail in section H of this proposed rule, we lacked the statutory and regulatory authority to recover those funds. These audits found that eligibility errors were largely attributable to caseworker and system errors, including States determining individuals to be ineligible but continuing to pay claims; incorrectly calculating income when determining eligibility; failing to verify income or resources; placing beneficiaries in incorrect eligibility categories; or not conducting required annual renewals.

Because of MEQC's limitations described in section F of this proposed rule and the need to strengthen oversight of Medicaid and CHIP beneficiary eligibility determinations, we propose to codify the Medicaid and CHIP beneficiary eligibility audits. These audits would help us better understand States' eligibility determination processes to better enable us to offer States recommendations and technical assistance to prospectively improve their eligibility determinations and, where appropriate, effect recoveries consistent with the requirements of section 1903(u) of the Act. These audits would be distinct from, and operate independently of, PERM eligibility reviews, with separate processes and purposes.[47] For example, these proposed eligibility audits would differ from PERM eligibility reviews in that they would not include the sampling and review of paid claims, but, instead, the sampling frame would consist of Medicaid and CHIP beneficiaries and applicants. Specifically, the sampling frame of enrolled Medicaid and CHIP beneficiaries would include those on whose behalf the State made Medicaid and CHIP payments for services during the audit period.

As opposed to State-run MEQC pilots that, as we explained, have not significantly reduced eligibility errors, our proposed expanded beneficiary eligibility audits would provide direct Federal oversight of States' Medicaid and CHIP beneficiary eligibility determinations. Because CMS and its contractors would conduct these Medicaid and CHIP beneficiary eligibility

[47] The PERM program measures the national Medicaid and CHIP improper payment rates through reviews of State's FFS, managed care, and eligibility components to comply with the Payment Integrity Information Act of 2019 (PIIA; Pub. L. No. 116-117). Additionally, PERM eligibility reviews currently measure eligibility improper payment rates in accordance with section 1903(u) of the Act. Each State is reviewed every 3 years, with 17-18 States reviewed annually.

audits, we expect States to have reduced administrative burden compared to the MEQC program. The Secretary, acting through CMS, is authorized by the Medicaid Integrity Program (MIP) at section 1936 of the Act to enter into contracts with eligible entities to carry out specific Medicaid oversight activities. Consistent with MIP provisions, States would be required to cooperate with CMS' contractors during the beneficiary eligibility audit process just as they are obligated to engage with CMS contractors during all Medicaid program integrity audits or reviews supporting MIP oversight efforts.

We are proposing to codify a regulatory structure for these Medicaid and CHIP beneficiary eligibility audits ensuring they would be consistent with the requirements of section 1903(u) of the Act and that would, in certain circumstances and as described in more detail in section III.H. of this proposed rule, permit us to pursue potential disallowances of FFP from States for overpayments identified in such audits. Previously, such disallowances were effectuated pursuant to the PERM program. We propose in section H of this proposed rule that we would issue eligibility-related disallowances in accordance with section 1903(u) of the Act for Medicaid and section 2105(e) of the Act for CHIP pursuant to these new beneficiary eligibility audits. Additionally, to improve our oversight effectiveness, we propose explicit regulatory authority by which we could require States to submit and implement CAPs to address eligibility errors identified during these audits to help them comply with Federal requirements.

Improper payment rates reported under the Payment Integrity Information Act of 2019 (PIIA)[48] would continue to be determined solely through PERM reviews, which occur on a routine triennial cycle covering 17-18 States each year and enable the calculation of a national improper payment rate. Conversely, the proposed Medicaid and CHIP beneficiary eligibility audits would prioritize high-risk States identified using a risk formula, though also ensuring that each State would undergo an eligibility audit at least once every 5 years.[49] Assuming our

[48] Pub. L. 116-117 (2020)

[49] As section 1903(u) does not apply to Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, or American Samoa, the territories are excluded from the proposed eligibility audit cadence and risk-based selection

proposals are finalized as proposed, we would articulate more information on the risk formula and the specific audit cadence via future sub-regulatory guidance. We believe that the PERM program, with its triennial cycle, is more appropriate for ongoing measurement of the national Medicaid and CHIP improper payment rates than the proposed eligibility audits, which, on average, would have longer intervals between audits.

The proposed eligibility audit process would allow CMS to review States' eligibility determinations with respect to individuals who are actively enrolled in or were denied enrollment or disenrolled from Medicaid or CHIP. Each beneficiary eligibility audit would include four statistically valid samples, two samples of active cases defined as individuals enrolled in Medicaid or CHIP, and two samples of negative cases defined as individuals who had been denied enrollment in or disenrolled from Medicaid or CHIP. Specifically, each audit would include a sample of active Medicaid cases, active CHIP cases, negative Medicaid cases, and negative CHIP cases. Any inaccurate eligibility determinations and deficiencies in documentation identified for sampled individuals would be reported to the State as soon as possible during the audit period to enable State correction and potential clarification. Notably, a beneficiary is entitled to Medicaid benefits unless and until a SMA determines them ineligible and provides advance notice of the termination and fair hearing rights.[50] Thus States would still be required to follow established procedures before disenrolling beneficiaries from Medicaid or CHIP due to audit findings. This proposed approach, coupled with the disallowance authority described in section H of this proposed rule, would provide us with greater oversight of Medicaid and CHIP beneficiary eligibility determinations, including State processes and the steps that States take to address any identified vulnerabilities.

This proposed rule would establish the requirements and procedures for the CMS Medicaid and CHIP beneficiary eligibility audits. Specifically, we propose to amend part 455 by

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methodology.

[50] §§ 435.917, 435.918, 435.930(b) and part 431, subpart E.

establishing a new subpart H (§ 455.700, *et seq.*), titled Medicaid and CHIP Beneficiary Eligibility Audit Program. For any Medicaid and CHIP beneficiary eligibility audits that may result in a disallowance of FFP, we propose that part 455, subpart H would apply to audits initiated after the completion of the PERM review period that is underway as of the effective date of the final rule (60 days after the publication).

Proposed § 455.700 would be authorized by sections 1903(u), 2105(e), and 1936 of the Act and articulate the basis and scope of these beneficiary eligibility audits aimed at reducing eligibility errors. We propose that during these audits, we would review States' Medicaid and CHIP eligibility processes and policies, and the appropriateness of eligibility determinations for sampled cases. Should our proposals be finalized as proposed, States would be required to participate when selected for an audit. To promote clarity and ensure consistent application of requirements, at § 455.702 we propose to define the following terms for purposes of this subpart: "corrective action," "eligibility," "eligibility audit," "eligibility determination," "eligibility error," "erroneous excess payments for medical assistance," and "observation." "Eligibility" would be defined as meeting the State's categorical, financial, and non-financial criteria for receipt of benefits under the Medicaid or CHIP programs. "Eligibility audit" would be defined as a CMS and Federal contractor conducted, primarily risk-based, audit of States' Medicaid and CHIP point of application or renewal eligibility determinations, designed to verify compliance with Federal and State eligibility requirements, reduce eligibility errors, and assist States in improving their eligibility determination processes. "Eligibility determination" would be defined with the same meaning as at § 435.4 for Medicaid and § 457.301 for CHIP, an approval or denial of eligibility in accordance with § 435.911 or § 457.340, as well as a renewal or termination in accordance with § 435.916 or § 457.344. "Eligibility error" would be defined as an error resulting from the State's improper application of Federal or State requirements, causing an improper beneficiary eligibility determination. For purposes of this definition, an eligibility error could include, but would not be limited to, authorizing an ineligible individual as eligible when

they received services, providing certain ineligible services to an otherwise eligible individual, improperly denying an individual's Medicaid or CHIP application, improperly terminating a beneficiary from Medicaid or CHIP, or enrolling in managed care an individual ineligible for managed care. "Erroneous excess payments for medical assistance" for purposes of these proposed eligibility audits would be defined as the term is defined in section 1903(u)(1)(D)(i) of the Act to mean the total of payments under the State plan (or waiver of such plan) with respect to ineligible individuals and families, and overpayments on behalf of eligible individuals and families by reason of errors in determining the amount of expenditures for medical care required of an individual or family as a condition of eligibility.[51] To comport with section 1903(u)(1)(D)(i) of the Act, only those erroneous payments meeting this definition would be factored into determining a State's error rates for purposes of potential disallowance arising from these audits, and thus any resulting disallowance amount. "Observation" would be defined as an instance where a beneficiary's or applicant's eligibility was correctly determined notwithstanding the State failing to follow Federal and State eligibility requirements. For example, an observation could occur where a State incorrectly calculated a beneficiary's income, but even when correctly calculated the beneficiary's income remained under the applicable income limit for Medicaid or CHIP coverage. "Corrective action" would be defined as a specific action that a State would be required to implement to address identified eligibility errors to achieve compliance with Federal requirements and Medicaid and CHIP State plans (or waiver of such plans). Corrective actions would only be required for eligibility errors identified during the beneficiary eligibility audit, not for standalone observations, and would be required regardless of whether the eligibility error had an associated erroneous excess payment amount.

At § 455.704, we propose the general requirements for Medicaid and CHIP beneficiary eligibility audits. Consistent with standard CMS audit practices, we propose that a State would

[51] Effective beginning in FY 2030, section 71106 of the WFTC legislation revised the definition for "erroneous excess payments for medical assistance" in section 1903(u)(D)(i) of the Act. Proximate to the effective date of the revised language we plan to do additional rulemaking to update the definition in § 455.702.

be required to participate in an eligibility audit upon notification that we were going to conduct such an audit, though allowing for limited exceptions for rare cases where a State could demonstrate experiencing extraordinary circumstances beyond the State agency's control making audit participation impracticable during the applicable fiscal year audit period. Every State would undergo a beneficiary eligibility audit at least once every 5 years. As discussed, more information on the specific audit cadence would prospectively be made available through sub-regulatory guidance. Outside of the audit cadence, we would prioritize States with Medicaid and CHIP programs determined to be at high-risk for eligibility errors for more frequent beneficiary eligibility audits, enabling us to focus our resources on States where eligibility errors were more likely to occur and reduce the burden on States consistently compliant with Federal and State requirements. We would identify for audit States at heightened risk for eligibility errors by conducting risk-based analyses informed by findings and data from sources including, but not limited to, prior PERM eligibility reviews, HHS-OIG audits, prior Medicaid and CHIP beneficiary eligibility audits, U.S. Government Accountability Office (GAO) reports, State Auditor reports, State-reported data, data analytics, and results from other ongoing CMS Medicaid and CHIP beneficiary eligibility oversight work. Our risk-based analyses would apply varying weights using a point system based on the risk associated with States making eligibility errors to the metrics drawn from such sources. This risk formula would assign each State a risk score, enabling us to compare States based on the number of risk points received and prioritize for audit those with the highest risk scores beyond the minimum 5-year audit cadence. The risk formula would be reviewed and updated annually by CMS to reflect change in any recent Federal Medicaid and CHIP eligibility laws or regulations. The same risk formula would be continually applied in a given year to identify States to prioritize for audit, while we would exclude those already being audited pursuant to the established cadence. In limited circumstances, we propose that we could select a State for audit regardless of its annual risk score were we to receive credible information regarding eligibility issues occurring in that State

requiring immediate oversight action. Sources of such credible information could include HHS-OIG audits and investigations, referrals, and other beneficiary eligibility oversight work conducted by CMS.

CMS would issue an engagement letter to the Medicaid director of a State selected for audit that specifies the audit objectives, scope, applicable disallowance authorities, data and documentation request, and corresponding data and documentation submission due dates. Pursuant to proposed § 455.704(b), States would be required to: (1) provide the requested eligibility and enrollment data (that is, the audit universe data) and documentation that could include, but not be limited to State policy manuals, eligibility operations manuals, eligibility training and guidance materials, and the State's verification plan within 10 business days from the engagement letter issuance date unless granted an extension by CMS; (2) assign at least two subject matter experts (SMEs) to navigate the necessary information contained in the State's eligibility and enrollment system(s) in coordination with the auditors during the case review portion of the audit to allow CMS to verify if eligibility determinations were made in accordance with Federal and State requirements for the sampled cases;[52] (3) provide requested copies of additional eligibility case records and any other necessary documentation within 5 business days of the written request unless granted an extension by CMS; (4) respond to the draft report in writing within 10 business days, unless granted an extension by CMS, indicating whether the State agreed or disagreed with each eligibility error cited; and (5) as applicable, submit CAPs for approval that would address each identified eligibility error by the deadline specified in the final audit report. The State's designated SMEs required under § 455.704(b)(2) would participate in scheduled case review sessions with the auditors to assist with providing the necessary supporting documentation within the State's systems for each sampled case. This approach would mean that State personnel would not have to train the auditors on their systems or provide

[52] As part of the beneficiary eligibility audit process, CMS and its Federal contractors do not request, access, or review Federal Tax Information (FTI). Where a State used FTI during an eligibility determination, we ask the State only to confirm that FTI was used and not show it to us.

them with system credentials. Based on experience with prior eligibility audits, this approach would reduce the overall burden on CMS and the State and allow CMS to more expeditiously and accurately complete the individual case review portion of the audit and communicate identified eligibility errors to the State, allowing it to more promptly correct identified issues. Pursuant to proposed § 455.704(b)(4), for any eligibility error with which the State would disagree, the State would have to provide a detailed written explanation of the basis for disagreement and submit supporting documentation to CMS to substantiate its position.

We propose that findings from our Medicaid and CHIP beneficiary eligibility audits would be subject to potential section 1903(u) of the Act eligibility-related disallowances at new § 455.706(d). Notably, as section 1903(u) of the Act is not explicitly listed in section 2107(e) to apply to a State's CHIP in the same manner that it applies to its Medicaid program, any eligibility-related disallowances for erroneous excess payments made on behalf of CHIP beneficiaries would be pursuant to the general payment recovery authority at section 2105(e) of the Act rather than 1903(u) of the Act. However, to ensure standardization across the Medicaid and CHIP programs, using our discretionary enforcement authority, CHIP samples in audits yielding findings subject to potential disallowance would still be treated in accordance with the requirements of section 1903(u) of the Act. That would include having an audit period covering a full fiscal year, a statistically valid random active case sample drawn from all eligibility categories included in the State's CHIP program during the audit period, and the calculation of a program-wide eligibility error rate.

Accordingly, we propose to make the requirements in new part 455, subpart H (§§ 455.700 through 455.712) applicable to CHIP in the same manner as they apply to Medicaid by amending § 457.628. The same audit methodology would therefore be used for the Medicaid and CHIP samples, ensuring consistent treatment between both programs.

Regardless of whether this proposal is finalized as proposed, we could still, as we do now, conduct other Medicaid and CHIP beneficiary audits that would not result in disallowances

and that could use different audit and extrapolation methodologies. Specifically, we may, as appropriate, conduct other Medicaid and CHIP beneficiary eligibility audits that use targeted methodologies to focus on a subset of eligibility categories or only disenrolled beneficiaries.

To ensure consistent treatment across States and compliance with section 1903(u) of the Act, at § 455.706 we propose the general audit methodology would apply to all States selected for beneficiary eligibility audits and would yield findings potentially subject to disallowance. For such audits, we propose to use statistically valid methodologies to select stratified random samples from a State's eligibility categories, calculate error rates, and extrapolate eligibility error rates to the entire universes of Medicaid and CHIP beneficiaries, and at § 455.706(a) we propose to codify general sample requirements. Every beneficiary eligibility audit would include four statistically valid random samples. As specified at new § 455.706(a)(1), one sample would include individuals enrolled in Medicaid whose eligibility was determined or redetermined and on whose behalf the State made payments for services provided during the full fiscal year audit period, while the second Medicaid sample would include individuals whose eligibility was denied or terminated during the audit period. The third sample would consist of individuals enrolled in CHIP whose eligibility was determined or redetermined and on whose behalf the State made CHIP payments for services provided during the audit period, while the fourth sample would consist of individuals whose CHIP eligibility was denied or terminated during the audit period. As proposed in § 455.706(a)(2), we would obtain the Medicaid and CHIP beneficiary and applicant data and their associated Medicaid and CHIP payments from the State's Medicaid and CHIP information systems, such as the Medicaid Management Information System (MMIS). The assigned State SMEs would provide this information to CMS auditors. As proposed in § 455.706(a)(3), we would use a statistical software package to generate random numbers to select Medicaid and CHIP samples from each corresponding stratum.[53] Strata would

[53] We currently use HHS-OIG's Office of Audit Services (OAS) statistical software package RAT-STATS for this purpose.

be nested within the program (Medicaid or CHIP) and established by statisticians based on, but not limited to, eligibility category, match rate, eligibility rules, and the dollar amount the State spent on services. As proposed at new § 455.706(a)(4), audit sample sizes would be designed to support statistically valid extrapolations of individuals associated with eligibility errors and their improper payments at a 90 percent confidence level, if applicable. For the active case samples, this would include individuals who did not meet eligibility requirements yet were improperly determined eligible and enrolled in Medicaid or CHIP and their associated payments for services during the audit period. For the negative case samples, this would include individuals who met eligibility requirements yet were improperly denied or disenrolled from Medicaid or CHIP. We propose using the lower limit of a 90 percent confidence level for these eligibility audits because 90 percent is consistent with longstanding HHS-OIG and Medicare extrapolation practices and would provide a conservative estimate accounting for statistical uncertainty.[54] Furthermore, we propose using a 90 percent confidence interval with a 5 percent precision level for the beneficiary eligibility audits, instead of a 95 percent confidence interval with a 3 percent precision level like the PERM program uses, to have smaller, more manageable audit sample sizes. Using a 95 percent confidence interval could require substantially larger sample sizes if we want to achieve greater precision, which would make the audit process more burdensome for States and CMS and mean that audits would take longer to complete.

Proposed § 455.706(b) specifies that we would use statistical software to, as applicable, estimate the total number of individuals with associated eligibility errors extrapolated to the entire Medicaid and CHIP universes based on findings from the active and negative samples, and the total extrapolated amount of erroneous excess payments made on behalf of the individuals who were improperly enrolled in Medicaid or CHIP and received services during the audit period based on findings in the active samples. We anticipate that we would use RAT-STATS for this

[54] Medicare Program Integrity Manual, Chapter 8 – Administrative Actions and Sanctions and Statistical Sampling for Overpayment Estimation.

purpose, but welcome comments regarding other statistical software that could be used. The statistical software would also be used to calculate the lower limit of the 90 percent confidence interval for the estimated numbers of individuals associated with eligibility errors and, where applicable, the total value of erroneous excess payments for medical assistance, as defined in section 1903(u)(1)(D)(i) of the Act and at proposed § 455.702.

At proposed § 455.706(c), we would calculate two error rates, one rate for Medicaid and one for CHIP, using the lower limit of the 90 percent confidence interval for the total dollar amount attributable to erroneous excess payments for medical assistance during the audit period. Each error rate would be calculated by dividing the total erroneous excess payments for medical assistance in the active sample by the total dollar amount associated with all individuals in the sample. This rate would then be statistically extrapolated to represent the overall error rate of erroneous excess payments for medical assistance for the State's entire Medicaid or CHIP population during the audit period. This proposal at new § 455.706(c) would, based on the results of the beneficiary eligibility audits, establish the path for us to determine Medicaid and CHIP eligibility error rates in accordance with the requirements of section 1903(u) of the Act. We would provide additional information on the statistical methodology in future sub-regulatory guidance.

We propose to add § 455.706(d) to specify that Federal payments associated with erroneous excess payments for medical assistance during the full fiscal year audit period could be subject to an extrapolated disallowance. We would issue such a disallowance in accordance with proposed § 455.802 and follow the requirements and procedures outlined in § 430.42. We propose that the eligibility error rates established in proposed § 455.706(c) could be used to determine the disallowance amount if above the section 1903(u) of the Act statutory allowable 3 percent eligibility error rate threshold. The eligibility error rates specified in § 455.706(c) would not include identified observations as those would not be subject to disallowances because beneficiaries' and applicants' ultimate eligibility determinations would have been found to be

accurate notwithstanding discerning some underlying calculation error. Our State audit engagement letter would, where applicable, include information about potential disallowances under sections 1903(u) and 2105(e) of the Act and new § 455.706(d).

We propose to add § 455.708 to clarify that protections of applicant and beneficiary information and due process rights, consistent with the provisions of 42 CFR part 431, subpart F, §§ 435.930(b), 435.917, 435.918, part 431, subpart E, and 457.1110 would apply during Medicaid and CHIP beneficiary eligibility audits. At new § 455.708(a) we propose that States would be required to safeguard applicant and beneficiary information and limit disclosures to information necessary to conduct the Medicaid and CHIP eligibility audits. We propose at § 455.708(b) that a State would be required to continue providing Medicaid benefits to eligible individuals in accordance with § 435.930(b) until it had made a final determination of ineligibility and provided advance notice and fair hearing rights.[55]

We also propose to add § 455.710 to make clear that States, upon our written request, would be required to provide CMS and its Federal contractors copies of eligibility case records for sampled cases and all available State policy and process documents related to eligibility determinations in effect during the beneficiary eligibility audit period. Requested documentation could include, but would not be limited to, State eligibility policy manuals, eligibility operations manuals, training and guidance materials, the State verification plan in effect during the audit period, and eligibility case record information that was not collected during the case review portion of the audit referenced at proposed § 455.704(b)(2).

At § 455.712, we propose that States would, as applicable, be required to submit CAPs in accordance with the proposed § 455.602 to implement corrective actions as specified in the final audit report. For each identified eligibility error, we would specify in the final report whether a corrective action was required, as we might determine in some instances that implementation of

[55] The State is required to provide advance notice and fair hearing rights in accordance with §§ 435.917–435.918 and Part 431, Subpart E.

corrective action was not necessary. Examples of such latter instances might include where a State had already implemented system changes or other corrective measures after the audit period that would prevent similar eligibility errors from recurring.

Where a CAP would be required, we propose that a State's CAP submission to us would need to clearly address the identified eligibility errors and the underlying causes of those errors. Pursuant to the proposed § 455.602 discussed further in section III.J. of this proposed rule, States' CAP submissions would require CMS approval, and, once a CAP had been approved, a State would be required to make sufficient progress implementing it within the CAP's established milestone timeframes. Requiring States to submit CAPs for our approval and implement approved CAPs within a specified timeframe would help them more expeditiously attain compliance with Federal requirements and reduce the likely recurrence of similar eligibility errors.

This proposed enhanced audit framework would address the key deficiencies in the existing MEQC program that we describe in section F of this proposed rule and that form part of the basis for our proposal to deregulate that program. These proposed provisions would provide us with greater oversight of States' Medicaid and CHIP eligibility determination processes and enable us to focus additional resources on high-risk States. We seek comment on this proposed audit strategy for Medicaid and CHIP beneficiary eligibility determinations, explicitly on the proposed minimum five-year audit cadence, feasibility for SMA personnel to meet the specified audit timelines, and inclusion of CHIP cases.

H. Medicaid and CHIP Beneficiary Eligibility-Related Disallowances

Section 1903(u) of the Act sets a 3 percent allowable threshold for program-wide eligibility improper payment rates in any full fiscal year after 1983, and specifies that the Secretary is generally required to disallow payments to States with respect to the amount of erroneous excess payments above that threshold.[56] However, the Secretary has the authority to waive all or part of the disallowance of FFP should a State be unable to reach the 3 percent allowable threshold despite a good faith effort to reduce its eligibility improper payment rate.[57]

The Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) added section 1903(u) to the Act.[58,59] Section 1903(u) was first implemented using the pre-existing Medicaid Quality Control (MQC) system, which was established in 1978 and reviewed the quality of eligibility determinations, third-party liability activities, and claims processing.[60] The MQC system consisted of six month sampling periods conducted by States to detect case errors, with State error rates verified using a Federal subsample.[61] The MQC system's eligibility review component became known as the MEQC program (referred to as the traditional MEQC program).[62] In 1992, the HHS Departmental Appeals Board (DAB) struck down the traditional MEQC disallowance methodology over concerns about the small sample sizes used to calculate error rates. In response, starting in 1994 we gave States the option to conduct MEQC pilots in place of traditional MEQC reviews.[63,64,65] States that elected to conduct MEQC pilots had their error rates frozen at the most recent traditional MEQC rate, as the pilots did not calculate error

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[56] Section 1903(u) of the Act does not apply to Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, or American Samoa.
[57] Under current regulations, a good faith effort means the State has taken the action it believed was needed to meet the allowable threshold and still failed to achieve that threshold. See § 431.1010(b)(2).
[58] Pub. L. 97-248
[59] 42 U.S.C. 1396b: Payment to States Amendments
[60] Medicaid Program; Reduction in Error Rate Tolerance; Medicaid Quality Control Program; Final Rule
[61] Medicaid Program; Reduction in Error Rate Tolerance; Medicaid Quality Control Program; Final Rule
62 Medicaid Program; Medicaid Eligibility Quality Control (MEQC) Program Requirements; Final Rule
[63] FY 1981 Medicaid Quality Control Disallowances, DAB No. 1332 (1992)
[64] Medicaid/CHIP Program; Medicaid Program and Children's Health Insurance Program (CHIP); Changes to the Medicaid Eligibility Quality Control and Payment Error Rate Measurement Programs in Response to the Affordable Care Act; Final Rule (82 FR 31158).
[65] GAO-20-157, *Medicaid Eligibility: Accuracy of Determinations and Efforts to Recoup Federal Funds Due to Errors*

rates. Over time, most States elected to conduct pilots as they provided States with more flexibility in the review design.[66]

With the publication of the July 2017 final rule titled, "Medicaid Program and CHIP; Changes to the Medicaid Eligibility Quality Control and Payment Error Rate Measurement Programs in Response to the Affordable Care Act," (82 FR 31158), we changed the mechanism for measuring and addressing Medicaid beneficiary eligibility errors under section 1903(u) of the Act from the MEQC to the PERM program. The codified MEQC program was revised to resemble the existing MEQC pilots, and we explained in the 2017 final rule that this would benefit States by allowing them to focus on refining and improving their eligibility determinations during the 2 off-years between PERM reviews, without using MEQC pilot findings as a basis for payment reductions or disallowances (82 FR 31158).

Under statute and current regulations, our authority to recover the Federal share of overpayments resulting from eligibility errors is limited to those over the 3 percent error rate threshold as identified through the PERM program.[67] Even in such instances, however, section 1903(u)(1)(B) of the Act and § 431.1010(b) permit CMS to waive a disallowance should a State be unable to reach the threshold despite a good faith effort. Specifically, per § 431.1010(b)(2) a State may qualify for a good faith waiver of disallowance if it (1) participates in the MEQC program in accordance with §§ 431.800 through 431.820; and (2) implements a PERM CAP in accordance with § 431.992. Conversely, a State's failure to comply with either requirement would be considered a failure to demonstrate a good faith effort. Although there have been instances where States' calculated eligibility error rates have exceeded the 3 percent threshold, to date we have granted good faith waivers from disallowances to any such affected States.[68] Should a State not meet the good faith waiver requirements, we would reduce its FFP for

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[66] Medicaid/CHIP Program; Medicaid Program and Children's Health Insurance Program (CHIP); Changes to the Medicaid Eligibility Quality Control and Payment Error Rate Measurement Programs in Response to the Affordable Care Act; Final Rule (CMS-6068-F)

[67] § 431.1010.

[68] Payment reductions/disallowances were able to be issued for PERM reviews starting on and after July 1, 2020.

medical assistance by the percentage by which the lower limit of its PERM eligibility improper payment rate exceeded the 3 percent threshold.

As discussed in section III.G. of this proposed rule, prior CMS beneficiary eligibility audits in seven States identified $231 million in potential extrapolated overpayments based on $2.9 million in sampled overpayments. When we conducted those audits, section 1903(u) of the Act was implemented solely through the PERM program and we were cognizant we would not have explicit regulatory authority to recover estimated overpayments, so we did not conduct them using methodologies designed to lead to full fiscal year disallowances under section 1903(u). As discussed in section G, we are proposing in §§ 455.700 through 455.712 to implement a Medicaid and CHIP beneficiary eligibility audit program that would operate independently from the PERM program and would be used to calculate error rates based on the total dollar amount attributable to erroneous excess payments for medical assistance and child health assistance, in a manner consistent with section 1903(u) of the Act. Accordingly, we also propose a disallowance framework for recovering overpayments identified through these eligibility audits when either the Medicaid or CHIP eligibility error rates exceeds the statutory threshold of 3 percent.

We propose to implement disallowances that meet the requirements of section 1903(u) of the Act pursuant to the proposed Medicaid and CHIP beneficiary eligibility audits that we would establish in new 42 CFR part 455, subpart H (as described in section G of this proposed rule) instead of under the PERM program established in part 431, subpart Q. We believe this approach would strengthen our ability to identify and recover erroneous excess payments and, by better holding States accountable when they make improper Medicaid and CHIP eligibility determinations, incentivize them in the first instance to make proper eligibility determinations.

We propose to remove the current PERM disallowance provision at § 431.1010 and, instead, establish comprehensive, unified eligibility-related disallowance regulations at 455 subpart I (§ 455.800, et seq.) that would only apply to the Medicaid and CHIP beneficiary

eligibility audits proposed under 455 subpart H. We propose to use this framework to issue disallowances in compliance with the requirements of section 1903(u) of the Act and § 430.42 based on eligibility error rates calculated during the Medicaid and CHIP beneficiary eligibility audits in accordance with new § 455.706(c). We propose that the requirements in subpart I would apply to Medicaid and CHIP beneficiary eligibility audits initiated after the completion of the PERM review period that is underway as of the effective date of the final rule.

To date, we have not issued any disallowances resulting from eligibility improper payment error rates identified through the PERM program primarily because all States with error rates above the 3 percent threshold have met the good faith waiver requirements at § 431.1010(b)(2), which include, in part, participation in MEQC pilots.[69] Should our proposal be finalized as proposed, the MEQC program would, after phase out, no longer exist (see section F of this proposed rule). Accordingly, we propose to replace the existing good faith waiver framework with new criteria in new § 455.804 that would establish the process and standards by which CMS could reduce, in whole or part, eligibility-related disallowances based on a State's demonstration of a good faith effort to meet the 3 percent allowable threshold while preserving CMS' discretion to deny such a waiver in cases of systemic or persistent program integrity failures.

Under proposed § 455.802(a), we would calculate potential disallowances using the eligibility error rates derived from a Medicaid and CHIP beneficiary eligibility audit subject to disallowance, with the disallowance(s) corresponding to the audit period (that is, the full fiscal year audit period). During a beneficiary eligibility audit conducted in a fashion by which it would be susceptible to our taking a disallowance, we would calculate two error rates, one for Medicaid and one for CHIP, for the total dollar amount attributable to "erroneous excess payments for medical assistance," as proposed at § 455.706(c).[70]

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[69] By its terms, the 2017 PERM final rule did not allow for such disallowances until review years ending after July 1, 2020.

[70] The error rate would be calculated by dividing the total erroneous excess payments for medical assistance in the

Under proposed § 455.802(b), we would calculate the potential Medicaid and CHIP disallowance amounts by subtracting the 3 percent allowable threshold from the lower limit of the State's error rates established in § 455.706(c), as determined through an eligibility audit subject to disallowance, and multiplying those results, if greater than zero, by the corresponding Federal share of medical assistance or child health assistance expenditures for the audit period. We propose to use the lower limit of the State's calculated error rates because that would be consistent with PERM and HHS-OIG extrapolation practices and provide reliable and conservative estimates of the true error rates accounting for statistical uncertainty. As discussed in the 2017 final rule (82 FR 31158), using the lower limit of the calculated Medicaid or CHIP error rate for disallowances would assist in ensuring there was reliable evidence that an error rate exceeded the 3 percent statutory threshold. These Medicaid and CHIP error rate calculations would result in potential extrapolated disallowance amounts consistent with section 1903(u) of the Act, and absent a good faith waiver, we would initiate disallowances in accordance with the procedures in § 430.42.

Section 1903(u)(1)(B) of the Act authorizes the Secretary to waive all or part of an eligibility-related disallowance where a State fails to achieve the statutory allowable threshold of 3 percent despite making a good faith effort to do so. Consistent with what we have articulated in prior rulemaking,[71] we believe a good faith determination should reflect both a State's efforts to establish and maintain appropriate controls before eligibility errors occur and its responsiveness after such errors are identified. As discussed, to date, we have granted good faith waivers from disallowances to every State that had an eligibility improper payment rate detected through the PERM program above the 3 percent allowable threshold. We propose to establish new good faith effort criteria, in part because one element of the current good faith waiver at §

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active sample by the total dollar amount associated with all beneficiaries in the sample and then statistically extrapolating this amount to determine the overall error rate of erroneous excess payments for the entire Medicaid or CHIP population.

[71] See, for example, the previously referenced PERM rulemaking at 82 FR 31158 ("We will grant a good faith waiver only if a State both participates in the MEQC pilot program and implements PERM CAPs.")

431.1010, participation in the MEQC pilot program, is proposed to be deregulated and replaced with the Medicaid and CHIP beneficiary eligibility audit program, and because we aim to require States to take more detailed, eligibility-focused actions to be granted a good faith waiver. Accordingly, we propose in § 455.804(b) that CMS would evaluate whether a State made a good faith effort using three complementary indicators. Specifically, we would evaluate whether a State: (1) implemented all elements associated with eligibility errors in its most recent CMS-approved PERM CAP in accordance with § 431.992; (2) where applicable, submitted and made sufficient progress implementing a CMS-approved CAP under proposed § 455.712 in response to previous beneficiary eligibility audit findings; and (3) undertook additional reasonable actions to prevent, identify, or mitigate eligibility determination errors it believed were necessary to fall within the allowable 3 percent statutory threshold. We would use these complementary indicators as a comprehensive and objective framework to determine a State's good faith waiver eligibility.

Under proposed § 455.804(b)(3), CMS would evaluate whether the State undertook additional reasonable actions to prevent, identify, or mitigate eligibility determination errors based on the totality of the circumstances. Relevant considerations could include, but would not be limited to, whether the State maintained reasonable pre-existing eligibility controls; whether the same errors had been identified in previous audits or reviews; the timeliness and substance of the State's response after error identification; any corrective actions already taken; and the State's cooperation and transparency during CMS audits and reviews. We would consider these factors collectively when assessing whether the State exercised reasonable diligence to prevent and address eligibility errors beyond satisfying the CAP requirements described in proposed § 455.804(b)(1) and (2).

We also believe that including a State's implementation of the eligibility-related elements of its most recent PERM CAP in accordance with § 431.992 and, where applicable, any previous CMS-approved beneficiary eligibility audit CAP under proposed § 455.712 as indicators of a

good faith effort would be appropriate and necessary because these corrective actions would represent a State's commitment to addressing eligibility errors and deficiencies identified through Federal oversight activities.

Under proposed § 455.804(c)(1), a State would, unless granted an extension by CMS, be required within 30 calendar days of CMS' issuance of a final audit report for a beneficiary eligibility audit and the associated potential disallowance amount to submit evidence demonstrating that its failure to meet the allowable threshold occurred despite a good faith effort to do so. A State could submit documentation such as policy manuals, staff training records, documentation of eligibility and enrollment system enhancements, self-audit reports, and detailed CAPs with proof of implementation and effectiveness. Should circumstances prevent a State from submitting such documentation within the proposed timeframe, it could submit a request for extension to CMS in writing and CMS could consider granting an extension commensurate with the extenuating circumstances. Pursuant to proposed § 455.804(a), CMS could grant a State a full or partial waiver based on the extent to which it demonstrated satisfaction of the proposed good faith criteria.

Under proposed § 455.804(d), CMS could determine that a State was not eligible for a good faith waiver, or was eligible for only a partial waiver, where the information and evidence available to CMS regarding the State's eligibility administration during the audit period demonstrated systemic or persistent program integrity failures inconsistent with a good faith effort to achieve the statutory allowable threshold. We believe that systemic or persistent program integrity failures may demonstrate that a State had not made a good faith effort as they indicate that known eligibility weaknesses were not abated despite prior opportunities to identify, correct, or mitigate those deficiencies. For example, CMS could consider whether similar eligibility deficiencies had been identified through previous audits, reviews, or other Federal oversight activities and if so, whether the State failed to take timely and effective corrective actions.

Proposed § 455.804(e) specifies examples of circumstances that CMS may consider in determining that a State had not demonstrated the good faith effort necessary to qualify for a full or partial waiver under section 1903(u)(1)(B) of the Act. These examples are intended to be illustrative of circumstances that may indicate systemic or persistent program integrity deficiencies but are not meant to constitute an exhaustive list or establish automatic disqualifying criteria. Such circumstances could include, but would not be limited to: repeated Medicaid and CHIP beneficiary eligibility audit or PERM findings involving the same or substantially similar errors; failure to address or implement prior CMS audit recommendations related to eligibility determination errors; known system defects, operational deficiencies, or policy weaknesses affecting eligibility determinations that remained unaddressed by the State during the audit period; or patterns of eligibility-related noncompliance identified through other Federal oversight activities, including audits, investigations, or findings by the HHS-OIG or other Federal agencies. These provisions would ensure that good faith waivers remain available for States demonstrating reasonable and proactive steps towards improving program integrity, while preserving CMS' discretion to deny a waiver or grant only a partial waiver where ongoing or unresolved deficiencies would undermine the integrity of eligibility determinations.

Proposed § 455.804(f) would establish the notification and timing requirements that would apply after CMS had made a good faith waiver determination. Under this provision, CMS would, via a single notice, notify each State with an eligibility error rate above the allowable threshold of its good faith waiver determination, including whether CMS had granted a full waiver, a partial waiver, or no waiver, and, where applicable, the amount of the disallowance. This written notification would also include the information specified in §430.42(a), as appropriate, including notice of the State's ability to seek reconsideration or appeal under proposed § 455.806 and § 430.42. We believe that providing States with a single written notification would promote transparency, ensure States would clearly understand the basis for

CMS' determination, reduce administrative burden, and provide the information necessary to make timely and informed decisions about whether to pursue reconsideration or appeal.

Proposed § 455.806 sets forth the process by which a State could appeal a disallowance imposed under §§ 455.802 and 430.42. Under this provision, a State that disagreed with a disallowance determination could seek CMS reconsideration or appeal the decision to the DAB within 60 calendar days after receipt of the CMS' final disallowance notice. We propose that all processes outlined in § 430.42 would govern disallowances issued under this section, including the processes for notice of disallowance, reconsideration, retention of funds during the pendency of an appeal, and appeals to the DAB in accordance with 1116(e) of the Act and § 430.42.

We explicitly seek comment on this proposed eligibility-related disallowance framework and new good faith waiver criteria.

I. Payment Error Rate Measurement (PERM) Corrective Action Plans (CAPs)

The PERM program measures and reports a national improper payment rate for Medicaid and CHIP in accordance with the requirements of the PIIA, which requires government agencies to identify, report, and reduce improper payments in the government's programs and activities. The implementation guidance in Appendix C of the Office of Management and Budget (OMB) Circular No. A-123[72] requires executive branch agency heads to review their programs and activities annually and identify those that may be susceptible to significant improper payments. For programs under our purview deemed susceptible to significant improper payments, we must obtain a statistically valid estimate of the annual amount of improper payments, implement a plan to reduce improper payments, and report annually in the Agency Financial Report. Through the measurement of three components, FFS, managed care, and eligibility, the PERM program annually yields estimates of Medicaid and CHIP improper payments via a longstanding 17-State-per-year,[73] 3-year rotation whereby each State is measured once every 3 years, not every year.

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[72] *https://www.whitehouse.gov/wp-content/uploads/2021/03/M-21-19.pdf.*

[73] Beginning with 2027 PERM reporting year (RY), Puerto Rico will participate in PERM's 3-year rotation used to measure improper payments. Cycle 3, including Puerto Rico, consists of 18 States (16 States, the District of

All 50 States and the District of Columbia are reflected in the national Medicaid and CHIP improper payment rates from the most recent three years of measurements. In FY 2025, the Medicaid and CHIP overall improper payment rates were 6.12 percent and 7.05 percent, respectively.

We take broad steps to reduce Medicaid and CHIP improper payments at the Federal level, but Medicaid and CHIP are Federal-State partnerships and States administer their Medicaid programs, therefore bearing primary responsibility to minimize and adequately address improper payments and their root causes. States, for example, must develop and implement State-specific PERM CAPs, with the existing process described at § 431.992. In accordance with the requirements at § 431.992(a), States are required to develop a separate CAP for Medicaid and CHIP for each improper payment rate measurement. Each CAP must be designed to reduce improper payments in the respective program based on the State's analysis of the causes of improper payments in the FFS, managed care, and eligibility components. Paragraphs (a)(1) and (2) require each plan to address all errors included in the State improper payment rate and all deficiencies and, for eligibility, to evaluate whether actions intended to reduce eligibility errors will also avoid increases in improper denials.

To meet the requirements at § 431.992(b), States' CAPs are required to include, at a minimum: (1) an analysis of errors associated with improper payments, (2) the corrective actions to be implemented to address the root causes of improper payments, (3) an implementation schedule for each corrective action that must include a plan for monitoring the effectiveness of corrective actions, and (4) an evaluation of the previous PERM-related corrective actions.

To meet the requirements at § 431.992(c), a State must submit a CAP to CMS following a PERM review, and implement it no later than 90 calendar days after CMS posts its Medicaid or CHIP improper payment rates on the CMS contractor's website. Section 431.992(d) requires a State to provide CMS annually, and upon request, CAP implementation progress updates.

Columbia, and the territory of Puerto Rico). The other two cycles consist of 17 States.

Section 431.992(e) requires that each State with an eligibility improper payment rate over the allowable threshold of 3 percent for consecutive PERM years submit updates on the status of corrective action implementation to us every other month. Status updates must include, but are not limited to the following: (1) details on any setbacks along with an alternate corrective action or workaround; (2) actual examples of how the corrective actions have led to improvements in operations, and explanations for how the improvements will lead to a reduction in the number of errors and in the State's next PERM eligibility improper payment rate; and (3) an overall summary on the status of corrective actions, planning, and implementation that demonstrates how the corrective actions will provide the State with the ability to meet the 3 percent threshold.

As discussed previously in this proposed rule, § 431.1010 outlines the criteria States must meet to be eligible for a good faith waiver of a disallowance under section 1903(u) of the Act when a State's PERM eligibility improper payment rate exceeds the 3-percent threshold. Section § 457.628(a) applies the PERM requirements, including the good faith waiver framework to CHIP in the same manner as Medicaid. These include implementation of PERM CAPs in accordance with § 431.992 and participation in the MEQC program in accordance with subpart P (§§ 431.800 through 431.820). As discussed elsewhere in this proposed rule, we propose to replace § 431.1010 with § 455.804. The proposed § 455.804 would establish the good faith waiver framework for disallowances arising from the proposed beneficiary eligibility audits. Under proposed § 455.804(b)(1) CMS would assess whether the State implemented the eligibility-related elements of its most recent CMS approved PERM CAPs in accordance with § 431.992.

1. State Submission of a Combined Medicaid and CHIP PERM CAP

Current PERM CAP regulations at § 431.992(a) require States to develop separate CAPs for Medicaid and CHIP errors and deficiencies (§431.992 applies to both programs). Through our experience administering PERM CAPs and working with States throughout the CAP development and review process, we have found the separate CAP submission requirement

creates inefficiencies for States and for CMS. We believe a more streamlined approach would reduce administrative burden and more effectively achieve PERM CAP goals.

The PERM program produces separate Medicaid and CHIP improper payment rates and there may be differences between a State's Medicaid and CHIP errors. Nevertheless, we have generally found that many State errors, root causes, corrective actions, implementation activities, and evaluation methods are either identical or share sufficient commonality that could be captured in a single PERM CAP. We have long observed that in many States the same staff develop, coordinate review, clear, and submit both plans. Our current process often requires States to enter the same background information in two plans, conduct separate internal clearance processes, and respond separately to similar CMS questions on materially similar submissions.

A combined submission would allow States to complete shared administrative information once, draft common corrective actions a single time, conduct one internal clearance process rather than two sequential ones, and present related corrective actions in a coordinated manner. We acknowledge that States with fully separate Medicaid and CHIP staff may realize more modest burden reduction. For those States, the combined format would be designed so that program-specific findings and corrective actions would be presented in clearly delineated separate sections, allowing each team to identify and work within their respective program's content without having to parse an undifferentiated document. We believe this structure would preserve the benefit of a single submission while minimizing the coordination burden on States with distinct program offices.

For CMS, a single submission would streamline receipt, tracking, review, and follow-up. It would also reduce duplicative requests for information and make it easier to assess whether corrective actions are being implemented consistently across Medicaid and CHIP. A consolidated format would continue to identify Medicaid and CHIP specific findings and

corrective actions in separate sections, as appropriate, so that CMS could independently evaluate compliance with the requirements applicable to each program.

We recognize the risk that a combined document could cause CMS or State staff to conflate Medicaid and CHIP requirements, findings, or corrective actions. To prevent that, the combined CAP format would require States to present Medicaid and CHIP specific findings and corrective actions in clearly labeled, separate sections. Where corrective actions would apply to both programs, States would be required to explicitly identify them as shared and confirm their applicability to each program independently. CMS reviewers would evaluate each program's section against the distinct statutory and regulatory requirements applicable to that program. We would provide States with a standardized template and accompanying guidance reinforcing that structure, and CMS staff would review combined submissions in a manner preserving independent program-level evaluation. These structural and procedural safeguards would be designed to ensure that consolidation of the submission format would not result in consolidation or confusion of the underlying program requirements. Accordingly, combining the plans would be an administrative simplification only, and would not merge, reduce, or otherwise modify the distinct statutory and regulatory obligations for Medicaid and CHIP.

We thus propose to amend § 431.992(a) to require States to submit a combined PERM CAP that would address, as applicable, Medicaid and CHIP PERM errors and deficiencies. The combined CAP would remain subject to all existing substantive requirements, including those at § 431.992(a)(1) and (2). We also propose a technical correction in paragraph (a)(1) to replace the cross-reference to § 431.960(f)(1) with § 431.960(f), which identifies the errors included in State improper payment rates.

Should our proposal be finalized as proposed, we would issue future operational guidance providing States with technical assistance for combining Medicaid and CHIP PERM CAPs, including examples.

2. Monitoring Implementation Progress and Evaluating the Effectiveness of Each Corrective Action

Current regulations at § 431.992(b)(3)(ii)(E) require that States' PERM CAPs include a plan to monitor the effectiveness of the corrective action. Under § 431.992(b)(4), States are required to submit an evaluation of the CAP from the previous measurement cycle that addresses the effectiveness of corrective actions by assessing improvements in operations, efficiencies, error rates, improper payments, and the ability to meet our assigned improper payment rate targets. In practice, we request implementation and evaluation updates from States approximately every 6 months, consistent with § 431.992(d), which requires States to provide updates at least annually, and more frequently if requested, on CAP implementation progress.

Through our experience administering the PERM CAP process, we have found that States' CAP submissions and subsequent evaluation submissions frequently fail to adequately detail how States will evaluate individual corrective actions for effectiveness and monitor implementation progress. Without a clear evaluation plan for each corrective action, we are unable to assess whether States' corrective actions are appropriately designed to address identified errors and States are unable to demonstrate measurable progress of their corrective actions over time. This limitation has resulted in recurring findings across PERM cycles, as States have implemented corrective actions that appeared responsive to identified errors but were not designed or evaluated in a manner that enabled us or the State to determine whether they were effective. Aiming to rectify that, we have issued PERM CAP guidance through templates and technical assistance, but those efforts have been inadequate to address this gap.

Accordingly, we are proposing two amendments to § 431.992(b)(3)(ii) to address these deficiencies. First, to clarify that the monitoring plan required for each corrective action must be designed to assess the progress of its implementation, not merely its effectiveness in the abstract, we propose to amend § 431.992(b)(3)(ii)(E) to read "A monitoring plan to monitor the progress of implementation of the corrective action." Second, we propose to amend § 431.992(b)(3)(ii)

by adding a new paragraph (F) to read: "A plan for evaluating the effectiveness of each corrective action that includes at a minimum the following: (1) Number of samples used for each evaluation; and (2) Frequency of each evaluation." Codifying these requirements in regulation would ensure that they apply uniformly across all State submissions and provide CMS with a clear regulatory basis to require States to revise CAP submissions that would not include adequate monitoring or evaluation plans. We believe it essential to add these requirements to ensure that States actively measure their CAPs' effectiveness and take steps to reduce future improper payments.

The proposed prospective evaluation plan would complement the retrospective evaluation required under § 431.992(b)(4). Paragraph (b)(3)(ii)(F) would require the State to explain at the outset how it intends to evaluate each corrective action, while paragraph (b)(4) would continue to require the State to report the results of its evaluation of the prior measurement's corrective actions. We are not proposing a separate submission or reporting process for the new evaluation plan requirement. Instead, we propose requiring this information as part of the CAP, enabling us and the State to identify any gaps early in the process. We believe this limited upfront requirement would represent the minimum information necessary to distinguish implementation monitoring from effectiveness evaluation and reduce the need for subsequent clarification and rework.

We believe that our proposals would clarify expectations, reduce administrative burden, and reinforce the intent of the PERM CAP framework of assisting States in developing, implementing, and evaluating effective corrective actions.

3. CMS Approval, Revision, Disapproval, and Implementation of State-Specific PERM CAPs

Our experience overseeing States' efforts to reduce Medicaid and CHIP improper payment rates across the PERM fee-for-service, managed care, and eligibility components has demonstrated that effective State implementation of PERM CAPs is critical to strengthening Medicaid and CHIP program integrity by identifying and addressing the root causes of improper

payments. Throughout the CAP development process, we provide guidance and work collaboratively with States to strengthen their understanding of PERM findings and the underlying causes of payment errors. We also provide States guidance on how to develop specific actions aimed at eliminating or reducing major errors, error trends, and repeat errors.

Notwithstanding our guidance describing the information States should include in their PERM CAPs, the existing regulatory framework does not establish a formal CMS approval process, uniform minimum standards for determining whether each required CAP element under § 431.992 has been sufficiently addressed, or process for requiring States to revise submissions that are incomplete, insufficient, or contain information requiring revision. In administering the PERM CAP process, we have encountered submissions that did not fully address one or more required elements or provide sufficient information to evaluate whether the proposed corrective actions were appropriately targeted and capable of being assessed for effectiveness. We recognize that this variation does not necessarily reflect a lack of State commitment to reduce improper payments. States vary in their program structures, available personnel and resources, information systems, and statutory and regulatory authorities. Moreover, certain corrective actions, particularly those requiring systems or legislative changes, may take substantial time to implement. Nevertheless, absent clear regulatory authority to review and approve PERM CAPs and require revisions when necessary, we cannot consistently ensure that each CAP meets a minimum standard to support meaningful corrective action and effective Federal oversight.

Accordingly, we propose to revise § 431.992(c) to establish a uniform approval and revision process that would set a minimum floor for the completeness and sufficiency of PERM CAP submissions while preserving State flexibility to develop and implement corrective actions that are appropriate to their unique circumstances. The proposed approval process would serve the purpose of ensuring that each CAP contains adequate information to support appropriately targeted corrective actions and meaningful Federal oversight. It would also establish a consistent process for determining whether each component-specific portion was approved, still under

review, or deemed disapproved. Specifically, proposed § 431.992 would govern CAP submission, review, approval, revision, and implementation, while proposed § 455.804(b)(1) would govern how CMS considers approval of the applicable eligibility portion and implementation of its corrective actions when assessing the PERM CAP condition for a good faith waiver. CMS would make these assessments separately for Medicaid and CHIP.

Under proposed § 431.992(c)(1), a State would be required to submit its combined Medicaid and CHIP CAP to CMS for approval and begin implementing corrective actions no later than 90 calendar days after CMS posts its Medicaid and CHIP improper payment rates on the CMS contractor's website. Because CMS posts both program rates on the same date, that date would start the initial submission and implementation period. This initial period is distinct from the 90-calendar day revision period that would begin with CMS' initial written notice of CAP issues under proposed § 431.992(c)(2)(i), discussed below. CMS would separately review the Medicaid and CHIP portions of the combined CAP and, within each program, separately review the eligibility and non-eligibility (fee-for-service and managed care) portions. CMS would approve each portion meeting the requirements of proposed § 431.992(a) and (b) and would notify the State in writing of each approval. CMS would follow the applicable procedures in proposed § 431.992(c)(2) before disapproving a portion. This component-specific structure would permit CMS to approve compliant portions independently and preserve separate program level review.

Under proposed § 431.992(c)(2)(i), if we determined that any portion of a State's proposed CAP failed to meet the criteria of proposed § 431.992(a) or (b), we would provide the State with an initial written notice identifying the issues in the CAP to be resolved. Such notice would include, for example, a request for additional information or other written communication clearly identifying the issues and revisions needed. The notice would identify the deadline for submission of the revisions and explain the approval and disapproval procedures applicable to that portion. For an eligibility portion, the notice would explain both the deemed disapproval

rule and the exception for a timely revised portion that remains under CMS review (described below). This initial written notice would be provided to the State even in those circumstances where no separate written determination would be required for deemed disapproval. The State would be required to revise and resubmit the affected plan or program specific portion, as requested by CMS, until attaining CMS' approval.

Under proposed § 431.992(c)(2)(ii), a State would have 90 calendar days from the date of CMS' initial written notification identifying issues under paragraph (c)(2)(i) to submit a revised CAP, or affected portion of the CAP, addressing the identified issues and satisfying the applicable requirements in proposed § 431.992(a) and (b). A revised submission would not restart the 90-day revision period. CMS would work with the State during that period and communicate in writing any remaining issues identified through its review. The State would be responsible for submitting an approvable revised portion by the deadline. The pending review exception described below would protect a timely revised eligibility portion that CMS had not finished reviewing from being deemed as disapproved. We anticipate that many States would be able to obtain CAP approval well before the end of the 90-day period, and would strongly encourage that, while the full timeframe would provide additional time for States to resolve more complex issues.

- Eligibility portions. Under proposed § 431.992(c)(2)(iii)(A), an eligibility portion not approved by the end of the 90-calendar day revision period would be deemed disapproved for the applicable PERM year, except when CMS review of the most recent revision submitted within that period would remain pending. When the exception would not apply, deemed disapproval would occur at the end of the correction period, without separate written notice of disapproval determination. Following a deemed disapproval, States would be required to continue working toward submission of an approvable eligibility portion of the CAP that meets the applicable requirements of proposed § 431.992(a) and (b) after the 90-day period had ended. CMS' subsequent written approval would supersede the earlier deemed disapproval of that portion for

the applicable PERM review year, as provided in proposed § 431.992(c)(2)(v). Such approval status would inform CMS' assessment under proposed under proposed § 455.804(b)(1).

- Pending CMS review exception. Under proposed § 431.992(c)(2)(iii)(B), CMS would communicate in writing when review of a timely revised eligibility portion remained pending at the correction deadline. That portion would remain under review, rather than be deemed disapproved, whether or not CMS had issued the status communication by the deadline. The status communication would neither approve nor disapprove the portion.

- Completion of pending CMS review. Under proposed § 431.992(c)(2)(iii)(C), CMS would approve the eligibility portion if it met the applicable requirements of proposed § 431.992(a) and (b). Otherwise, CMS would issue a written disapproval identifying the unmet requirements. The disapproval determination would take effect when CMS issued the written notice.

- Non-eligibility portions. Under proposed § 431.992(c)(2)(iv), fee-for-service and managed care portions would remain subject to CMS review and approval, but the eligibility-specific deemed disapproval rule would not apply. After the revision period and completion of its review, CMS would issue a written disapproval identifying the unmet requirements for any non-eligibility portion that does not meet proposed § 431.992(a) and (b). The disapproval would take effect when CMS issued the notice. The failure to obtain approval of a non-eligibility portion of the combined CAP within the 90-calendar day revision period would not affect whether the State satisfied the Medicaid and CHIP eligibility portion of the PERM CAP condition for a good faith waiver under proposed § 455.804(b)(1).

- Continuing obligation and later approval. Under proposed § 431.992(c)(2)(v), a State would remain required to revise and resubmit each unapproved CAP portion until CMS approval, including after the revision period or a deemed or written disapproval. This continuing obligation would apply to both eligibility and non-eligibility portions.

We also propose to clarify States' implementation obligations before and after CMS approval. Under proposed § 431.992(c)(3), a State would be required to begin implementing the corrective actions within the initial submission period and follow the implementation schedule in its most recently submitted, unapproved CAP while CMS review was pending, including during the revision period and after a disapproval unless CMS directed the State in writing to defer, modify, or discontinue a specific action. Revision or disapproval of one portion would not, by itself, require the State to restart corrective work in another portion or repeat work consistent with the approved CAP. CMS would request additional information or revisions to an affected CAP portion as necessary to address the identified issues and determine whether that portion meets the requirements of proposed § 431.992(a) and (b). This would limit requests to information needed for review while allowing changes to an action CMS finds insufficient or inappropriate.

Together, the initial written notice, defined revision period, independent approval of compliant portions, pending-review protection, and continuing revision and implementation requirements would make the process more predictable and limit unnecessary work. Deemed disapproval would apply only to eligibility portions as provided in proposed § 431.992(c)(2)(iii)(A). A timely revised eligibility portion still under review at the revision deadline would remain pending until CMS approved it or issued the written disapproval described in proposed § 431.992(c)(2)(iii)(C).

We seek comment on the proposed approval, revision, disapproval, and implementation process, including the 90-calendar-day revision period, the distinction between deemed and written disapproval, the pending-review exception and status communication, and the treatment of later approval in the good faith waiver assessment. We also seek comment on whether the requirements of § 431.992(a) and (b) provide States sufficient clarity to develop approvable CAPs. Should there be such need, we may address any such concerns through future rulemaking or the issuance of additional guidance.

4. Semi-Annual Reporting Requirements for States with an Eligibility Improper Payment Rate Above 3 Percent for Consecutive Cycles

Current PERM CAP regulations at § 431.992(e) require States with a Medicaid and/or CHIP eligibility improper payment rate over the 3 percent allowable threshold for consecutive PERM years to submit updates to CMS every other month on the status of eligibility-related corrective action implementation. Sections 431.992(e)(1) through (3) require States to provide the following information: (1) details on any setbacks along with an alternate corrective action or workaround; (2) examples of how the corrective actions have led to improvements in operations, and explanations for how the improvements will lead to a reduction in the number of errors and the State's next PERM eligibility improper payment rate; and (3) an overall summary on the status of corrective actions, planning, and implementation that demonstrates how the corrective actions will provide the State with the ability to meet the 3 percent threshold.

We have found over time that this every other month reporting cadence is excessive, as it does not permit States the necessary time to implement and evaluate corrective action effectiveness in a meaningful way. We believe we could better attain the goals of an enhanced reporting requirement while reducing State and CMS burden with a less frequent reporting cadence that would allow States longer to evaluate the effectiveness of corrective actions and report on their status and outcome.

Accordingly, we propose to implement a biannual (every 6 months) reporting requirement for States with a Medicaid and/or CHIP eligibility improper payment rate over the 3 percent allowable threshold for consecutive PERM years, which would begin 2 months after our formally approving a State's PERM CAP. We believe that new reporting cadence would be a more rational approach better reflecting operational realities within a State. We also believe that the 2-month interval before the first report needs to be submitted would provide States a reasonable period to begin implementing approved corrective actions before the first status update would be due, rather than requiring a report before implementation had meaningfully

begun. We further propose to end a States' reporting obligation before we post the State's improper payment rate for the next applicable PERM cycle, reflecting the inherent lag between the conclusion of corrective action reporting and the availability of new rate data that would determine whether the State had met the 3 percent threshold. We believe that anchoring the start and end of the reporting obligation to these two events—formal CAP approval and the posting of the next cycle's improper payment rate—would provide States an attainable timeline and avoid a reporting requirement extending into a period when new performance data would better demonstrate a State's progress than would status updates.

We recognize that States may face consecutive PERM cycles in which their eligibility improper payment rate remains over the 3 percent threshold, requiring approval of a new or updated CAP for each subsequent cycle. We propose that each such reporting window be cycle-specific, meaning that a new 6-month reporting period would begin based on CMS' approval of the CAP for that subsequent cycle, rather than treating reporting as a single continuous obligation spanning multiple PERM cycles. This approach would ensure that each reporting window would reflect the specific corrective actions approved for that cycle, and avoid confusion where a State's reporting obligations might otherwise overlap or become disconnected from the CAP actually in effect.

We also propose to clarify the scope of the required status updates when only one program would exceed the 3 percent threshold. Because § 431.992(e) would apply when a State's Medicaid and/or CHIP eligibility improper payment rate would exceed the allowable threshold, a State could exceed the threshold with respect to just one program. In such a circumstance, we propose to require that the State's status updates address only the program exceeding the threshold, irrespective whether both are out of compliance. We believe this approach would appropriately focus the reporting requirement on the program for which corrective action would be needed while avoiding the unnecessary reporting burden for a program whose improper payment rate would be within the allowable threshold. We seek

comments on whether the every 6 months reporting period is an appropriate length of time or if the time period should be decreased.

J. Program Integrity CAPs

Several provisions of section 1902 of the Act address States' responsibilities related to Medicaid program integrity, including requirements concerning the proper and efficient administration of the State plan and safeguards against unnecessary utilization and inappropriate payments. Section 1936 of the Act established the MIP, authorizing the Secretary to contract with eligible entities to conduct audits, investigations, education, and training in support of State anti-fraud efforts. Through these authorities, CMS conducts audits of various areas of risk or vulnerability, including State program integrity audits of high-risk service areas, beneficiary eligibility audits, and Medical Loss Ratio (MLR) audits, all of which may result in findings and recommendations requiring States to take specific corrective actions. Currently, when a program integrity audit identifies a State as out of compliance with Federal Medicaid requirements, CMS issues a final audit report describing the findings of noncompliance and recommended corrective actions for the State to address and correct the identified deficiencies. As part of such CMS oversight activities, we often request that States develop and submit CAPs to address identified findings. CMS also works collaboratively with States to provide technical assistance and education, including through the Medicaid Integrity Institute (MII), and works with States to develop and oversee their CAPs at the conclusion of PERM reviews.

Despite our robust Medicaid and CHIP oversight and continuous improvement efforts, we continue to identify recurring State program integrity operation errors that manifest in repeat audit findings.[74] For example, our State Program Integrity Audits have historically assessed States' compliance with Federal Medicaid FFS (part 455, subparts A to F) and managed care (part 438, subparts A to K) program integrity standards. Even in States that have previously

[74] CMS' State Program Integrity Review reports are available on the CMS website, here: *https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/FraudAbuseforProfs/StateProgramIntegrityReviews.*

developed and implemented CAPs, too often these State Program Integrity Audits identify significant and repeat findings. Common areas of regulatory non-compliance include managed care contract compliance, high-risk provider identification, lapses in conducting independent audits, managed care overpayment reporting requirements, payment suspension policies/procedures, and verification of beneficiary services. In addition, we have encountered challenges obtaining timely and complete corrective action from States following State Program Integrity Audits. For example, States have sometimes failed to submit or revise CAPs in a timely fashion, provide requested information regarding implementation progress, or meet timelines established through the audit follow-up process. Our existing regulations do not establish a uniform mechanism for requiring and overseeing CAPs in such situations. Recurring audit findings, particularly when States fail to adequately take corrective action, underscore our need for a clearer and more consistent regulatory framework defining State obligations to develop and implement CAPs in response to CMS audit findings and providing specific regulatory requirements against which to assess States' compliance.

Accordingly, pursuant to the Secretary's general rulemaking authority under section 1102 of the Act and the Medicaid administrative authority under section 1902(a)(4) of the Act, we propose to establish standardized regulatory requirements governing program integrity CAPs to ensure that States identify and address programmatic vulnerabilities and findings of regulatory non-compliance identified through CMS oversight activities. Specifically, we propose to amend 42 CFR part 455 by adding a new subpart G (§ 455.600, *et seq.*), titled Requirements for Program Integrity Corrective Action Plans. These proposed requirements would be intended to promote greater consistency, transparency, and accountability in how States identify and correct deficiencies identified in the Medicaid program through CMS program integrity oversight activities. The proposals in this Subpart would apply exclusively to Medicaid; CHIP corrective action would continue to be governed by applicable provisions of part 457.

We propose to add a new § 455.602 establishing standardized requirements governing Program Integrity CAPs, including when a CAP would be required, the information it would be required to contain, CMS review and approval procedures, and State implementation and monitoring responsibilities. Under proposed § 455.602(a), when a CMS State Program Integrity Audit identifies Medicaid statutory or regulatory requirement noncompliance, our final audit report would identify the findings, if any, for which the State would be required to develop a Program Integrity CAP. Not every finding of noncompliance in every audit would necessarily require a CAP. For example, we may determine that a CAP is unnecessary when a State demonstrates that it has fully corrected the identified deficiency before issuance of the final audit report and no further corrective action or monitoring is necessary to bring the State into and maintain compliance with the applicable Federal requirement. Where we would determine that a CAP was necessary for one or more findings, our final audit report would identify those findings and the State would be required to develop a single program integrity CAP addressing each finding for which corrective action was required.

We propose in new § 455.602(b) to define four criteria that States would have to include in each Program Integrity CAP and that would serve as a basis for us to evaluate its appropriateness. Satisfying these four criteria would be necessary to ensure that implementation of the Program Integrity CAP could meaningfully and effectively mitigate the identified program integrity risks, with the ultimate goal of reducing future Medicaid improper payments and fraud, waste, and abuse. Similar to the PERM CAP requirements specified at § 431.992(b), we propose at § 455.602(b) that each program integrity CAP would be required to include the following elements: (1) a root cause analysis to identify the specific programmatic causes to which each finding of noncompliance would be attributed; (2) the specific corrective action(s) that would be implemented to address each finding of noncompliance and bring the State into compliance; (3) an implementation schedule for each corrective action that would have to include an estimated timeline for implementation, contact information for key personnel responsible for

implementation, and a monitoring plan to track the status and progress of implementation of the corrective action; and (4) a plan for evaluation of the effectiveness of each corrective action and how it would rectify the finding(s) of non-compliance.

We propose at § 455.602(c) that if the final audit report requires a program integrity CAP under paragraph (a) of this section, the State would be required to submit the CAP to CMS no later than 30 calendar days after the date of the final audit report, unless we were to grant a good-cause extension. While the proposed 30-day timeframe would be shorter than the 90-day PERM CAP timeframe under § 431.992(b), the program integrity audit and review process would differ from the PERM review process as the audit and review topics would be much narrower and States would review and provide responses to draft audit reports in advance of the issuance of final audit reports. As such, we believe States would be able to submit any required program integrity CAP within 30 calendar days of the date on the final audit report. We seek comment on this proposed timeframe, including whether and in what circumstances an extension might be appropriate.

Based on our experience with implementing PERM program corrective actions and other oversight efforts, we believe a CAP approval process would strengthen the CAP framework by helping ensure that CMS and States have a shared understanding of how findings and vulnerabilities would be addressed and mitigated. We propose to include a new § 455.602(c)(1) that would require States to submit program integrity CAPs to CMS for review and approval. Should CMS determine that a submitted CAP would not adequately address the audit findings or otherwise fail to satisfy the requirements of §455.602(b), CMS would return the CAP to the State for revision and resubmission. We believe this review process would help ensure that approved CAPs were sufficient to address the deficiencies identified in the audit.

Further, to ensure that States would satisfactorily implement and execute the actions described in their approved program integrity CAPs, we propose at new § 455.602(c)(2) that States would be required to provide updates and verify the effectiveness of their CAP

implementation at every milestone deadline established in the approved CAP and upon request by CMS. We would establish that frequency in our notice of approval of the State's CAP.

Finally, we propose at § 455.602(d) to clarify that the proposed Program Integrity CAP framework would not limit, delay, or condition CMS' exercise of any administrative action otherwise authorized under Federal law. Accordingly, where the applicable requirements for another administrative action are satisfied, CMS could, as appropriate, pursue such an action before, concurrent with, or after requiring a Program Integrity CAP. For example, section 1904 of the Act authorizes the Secretary, after reasonable notice and opportunity for hearing, to withhold further payments to a State upon determining that the State plan no longer complies with the requirements of Section 1902 of the Act or that the State's administration of the plan fails to comply substantially with those requirements. Accordingly, were CMS to determine that the applicable requirements for a withholding under section 1904 of the Act and § 430.35 were satisfied, the proposed Program Integrity CAP process would not require CMS to await completion or failure of a CAP before pursuing withholding. This proposal would not expand or otherwise modify the Secretary's existing withholding authority under section 1904 of the Act, § 430.35, or any other existing authorities. We seek comment on these proposals.

K. Medicaid Fee-for-Service (FFS) Overpayment Reporting (60-Day Rule)

Section 1128J(d)(1) of the Act requires a person who has received an overpayment to report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate. The Act also requires that person to notify, in writing, the entity to which it returns the overpayment of the reason for the overpayment. Section 1128J(d)(2) of the Act requires individuals receiving overpayments under Medicaid or Medicare to report and return the overpayment by the later of (i) 60 days after the date on which the overpayment was identified; or (ii) the date any corresponding cost report is due, if applicable. Section 1128J(d)(3) of the Act specifies that any overpayment retained by a person after the deadline for reporting and returning an overpayment is an obligation subject to enforcement under the False

Claims Act (FCA) (as defined in 31 U.S.C. 3729(b)(3)). Under section 1128J(d)(4)(C)(i) of the Act, the term "person" refers to any provider of services, supplier, Medicaid managed care organization, Medicare Advantage organization, or Prescription Drug Plan sponsor. Section 1128J(d)(4)(C)(ii) of the Act excludes beneficiaries from the definition of person.

Section 1903(d)(2) of the Act and § 433.312 outline States' obligations, with certain exceptions, to return the FFP associated with provider overpayments within a specified timeframe, regardless of whether they have successfully recovered those overpayments. This regulatory framework ensures State accountability and the appropriate management of Federal funds.

This proposed rule would implement the requirements of section 1128J(d) of the Act for the reporting and returning of overpayments in Medicaid FFS, the remaining CMS program to which this statutory provision applies for which regulatory requirements have not been issued. We previously issued rules implementing the requirements of section 1128J(d) of the Act in the Original Medicare (42 CFR part 401, Subpart D), Medicare Part C & D Risk Adjustment Data (§ 422.326), Medicare Part D (§ 423.360), and Medicaid Managed Care (§ 438.608) programs. To best ensure consistent application of the same provision of law across CMS programs, these proposed policies are modeled upon the Medicare FFS regulations found at § 401.305.

Consistent with this statutory requirement that arises outside of the Medicaid Act (instead, at Title XI of the Act), this proposal would establish direct requirements on Medicaid providers (which is atypical for our Medicaid regulations) by specifying a timeframe by which a person must report and return overpayments to the State and establish a standard for when an individual has identified an overpayment. Consistent with regulations at §§ 433.320 and 433.322, our proposal would also require that States keep account of the overpayments identified and returned by providers, produce those records to us upon request, and report to us the amounts of returned overpayments to us on the CMS-64 (Quarterly Medicaid Statement of Expenditures for the Medical Assistance Program) for purposes of adjusting the State's claims for FFP. The

proposed requirements would be intended to ensure compliance with applicable statutes and protect the Medicaid program against fraud and other improper payments. To implement these requirements, we propose to create a new part 455 subpart J (§ 455.900, et seq.), titled Reporting and Returning of Overpayments in Medicaid Fee-for-Service. Section 1128J(d) is limited to overpayments under titles XVIII and XIX, so the requirements of this proposed rule would not apply to CHIP.

Mirroring the statutory definition, we propose at new § 455.902 to define an "overpayment" as any funds that a person received or retained under title XIX of the Act to which the person is not entitled under such title after applicable reconciliation. Also consistent with the statute at section 1128J(d)(4)(C), we propose to define "person" as a provider of services or a supplier that participates under a State plan (or waiver of such plan) established under title XIX of the Act, thus excluding Medicaid beneficiaries from the definition. Although the term 'supplier' is not commonly used in Medicaid, we propose to include it in the definition of 'person' to track the statutory language at section 1128J(d)(4)(C) of the Act.

Consistent with the statutory requirements in section 1128J(d)(1)(A) and (B) of the Act, we propose at new § 455.904(a)(1) that a person that has received an overpayment must report and return it to, and in a form and manner specified by, the State, and include a written reason for the overpayment. Similar to Original Medicare regulations at § 401.305, we propose at new § 455.904(a)(2) that a person has identified an overpayment when the person knowingly receives or retains an overpayment, and that the term "knowingly" has the meaning set forth in 31 U.S.C. 3729(b)(1). Specifically, under the proposed rule, a person would have identified an overpayment if they had actual knowledge of the existence of the overpayment or acted in reckless disregard or deliberate ignorance of the overpayment. This proposed standard for an "identified overpayment" would align with the statutory obligation in section 1128J(d)(4)(A) of the Act, which provides that the terms "knowing" and "knowingly" have the meaning given those terms at section 31 U.S.C. 3729(b)(1) of the Federal civil False Claims Act.

Also similar to Medicare FFS regulations at § 401.305(b), we propose at new § 455.904(b) that a person who has received an overpayment from a Medicaid FFS program must report and return the overpayment to the State by the later of: (i) 60 days after the date on which the overpayment was identified, or (ii) the date any corresponding cost report is due, if applicable. These proposed timeframes mirror the statutory requirements at section 1128J(d)(2) of the Act.

Additionally, we propose at new § 455.904(c)(1) that States would be required to establish a mechanism for a person to report to the State when an overpayment was identified. We also propose to specify at new § 455.904(c)(2) that States would be required to return the Federal share of the overpayments to us on the CMS-64 for purposes of adjusting the State's claims for FFP consistent with current requirements. Because overpayments are not eligible for FFP, the Federal share of any identified overpayments would need to be refunded to us and adjusted through the State's normal financial adjustment process. Under existing regulations at part 433, subpart F, and subject to limited exception, a State has 1 year from the date of discovery of an overpayment to recover or seek to recover the overpayment before the Federal share must be refunded to us, and importantly the State must refund the Federal share of the overpayment to us irrespective of whether the State has recovered the overpayment from the provider. This proposed rule would not alter these existing requirements. Similar to regulations at § 433.322, we also propose at new § 455.904(c)(3) that States would be required to maintain all records related to overpayments. We also propose at new § 455.904(d) that a person would be required to use the reporting mechanism established by the State to report and return an identified overpayment. Similar to related Original Medicare regulations, we propose that any person reporting and returning an overpayment calculated via a statistical sampling methodology and extrapolation would be required to describe that statistically valid sampling and extrapolation methodology in their report to the State, which the State would be required to maintain and make available to CMS upon request pursuant to paragraph (c)(3).

In addition, consistent with section 1128J(d)(3) of the Act, we propose at new § 455.904(e) that any overpayment retained by a person after the deadline for reporting and returning it would be considered an obligation for the purposes of the False Claims Act (FCA) at 31 U.S.C. 3729(b)(3).

Finally, we propose at new § 455.904(f) that overpayments would be required to be reported and returned to the State only if a person identifies the overpayment within 6 years of the date the overpayment was received. This limitation on the lookback period would be necessary to avoid imposing an unreasonable burden or cost on providers and would be consistent with related Original Medicare regulations at § 401.305(f). We seek comment on this lookback period and whether a longer or shorter lookback period would be more appropriate to address State-specific processes, such as whether there are claim/cost-report reopening limitations that could impact overpayments that would otherwise be required to be reported and returned.

Importantly, and notwithstanding our proposal to codify statutory requirements, Medicaid providers are, and since its enactment have been, subject to section 1128J(d) of the Act's statutory overpayment report and return provisions and could face potential FCA liability, Civil Monetary Penalties Law (CMPL) liability, and exclusion from Federal health care programs for failing to report and return an overpayment. Additionally, Medicaid FFS providers must continue to comply with States' current procedures when States identify an overpayment and issue a demand letter. Medicaid FFS providers are also responsible for ensuring their Medicaid claims are accurate and proper and are encouraged to have effective compliance programs to avoid receiving or retaining overpayments. Should this rule be finalized as proposed, the overpayment-related requirements would be applicable to States 6 months after publication of the final rule. We invite comment on these proposals.

L. Medicaid and CHIP Managed Care Oversight Policies

1. Background

Beneficiaries enrolled in Medicaid managed care plans receive part or all of their Medicaid services from health care providers that are paid by managed care plans under contract with the State. In return, the managed care plan usually receives a per member per month (PMPM) payment, commonly referred to as a capitation payment, from the SMA for providing a specified benefit package. These are known as risk-based arrangements, where the capitation payment rate must be actuarially sound and projected to provide for all reasonable, appropriate, and attainable costs as required by the terms of the contract (438.4(a)). Managed care plans receive capitation payments, usually monthly, for each "Medicaid-eligible enrollee" (§ 438.3(c)(2)) regardless of whether the enrollee utilizes services that month. Capitation rates also account for certain administrative costs, including program integrity operations. States are required to specify in their contracts with managed care plans the applicable policies governing the disposition of recovered overpayments, including whether a plan may retain a recovered overpayment or must remit it to the State.[75] Those retention policies do not apply to recoveries retained under the FCA or through other Federal investigations, including other investigations by CMS and its contractors where the Federal government retains any recovered FFP.[76]

As part of our ongoing efforts to strengthen Medicaid program integrity, we have identified several risks and vulnerabilities that may contribute to Medicaid managed care overpayments. These include issues related to the definition of "Medicaid-eligible enrollee," the requirements and timeframes for managed care plans to report changes in enrollee circumstances to the State, and the circumstances under which States must return the Federal share of Medicaid managed care overpayments to CMS. Having identified these issues, we propose rulemaking here to address these risk and vulnerabilities.

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[75] § 438.608(d)(1).
[76] § 438.608(d)(1)(iv).

a. Medicaid and CHIP Eligibility Determination Requirements for Beneficiary Residency and Death

For most beneficiaries, under titles XIX and XXI of the Act and implementing regulations, Medicaid and CHIP eligibility is subject to periodic renewal, generally on an annual basis or every six months depending on eligibility category.[77] Separately, States conduct eligibility redeterminations when there is a change in a beneficiary's circumstances that may affect eligibility. For example, a beneficiary moving out of a State or dying would prompt an SMA to redetermine eligibility.[78] States may learn of such change in circumstance through a variety of sources, including Federal and State databases, another SMA, a managed care plan, or, with respect to an out-of-State move, possibly a beneficiary him or herself.

Managed care plans in Medicaid and CHIP are subject to reporting requirements under § 438.608(a)(3) to promptly notify the State when they receive information about changes in an enrollee's circumstances that may affect eligibility. Once notified, the State must redetermine the beneficiaries' eligibility, which involves multiple steps and sometimes may be a multi-month process. Based on the type of reported change, the State may require additional information from a beneficiary (or their family or representative) and must provide them with a reasonable time to respond. Should a State determine that a beneficiary is ineligible, it must provide the beneficiary advance notice and fair hearing rights as appropriate under §§ 435.917 and 918; § 435.952(d), as applicable; and Part 431 Subpart E, including the 10-day advance notice requirement in § 431.211, subject to applicable exceptions. Because the State must consider eligibility on all bases before determining ineligibility under § 435.916(f)(1) and must continue to furnish Medicaid to eligible individuals until they are found to be ineligible under § 435.930(b), the State may keep the enrollee in a managed care plan and continue to make

[77] https://www.federalregister.gov/d/2026-11094. For the period until October 1, 2034, this IFC restores the following regulations as they existed before the 2024 Eligibility and Enrollment final rule: §§ 431.213(d), 431.231(d), 435.907, 435.911(c), 435.912, 435.916, 435.919, 457.340(d)(1), 457.344, and 457.960

[78] § 435.916(d)

capitation payments until the beneficiary's eligibility is terminated[79] or they are disenrolled from the plan and enrolled in the State's FFS program.

States have the option to contract with a managed care plan to cover beneficiaries in the entire State or to cover only those within a certain geographical area within the State. This creates State-specific circumstances where a change in address may impact a beneficiary's enrollment in managed care. For this reason, SMAs must clearly communicate to beneficiaries the importance of timely reporting changes in residence and must promptly act on reported changes to maintain accurate managed care enrollment and ensure that capitation payments align with applicable service area requirements when the change would trigger a redetermination of Medicaid eligibility. However, typically, moving within a State would not be considered a "change in circumstance" resulting in a redetermination of eligibility. However, as stated earlier, managed care enrollment may be affected by an in-State move, and therefore, may require the SMA to change a beneficiary's enrollment in a managed care plan if they are unable to access their existing provider network and covered services, or no longer live within the managed care plan's contracted service area.

States have broad flexibility to determine how they identify beneficiaries who are deceased. Currently, Federal requirements do not mandate that SMAs' eligibility systems routinely interface with a specific source to obtain death data; however, many States rely on Federal, State, or local databases that contain death data, such as State or local vital records systems. The Social Security Administration maintains a national record of death, the Death Master File (DMF), which is updated monthly with beneficiary death information. In 2024, to facilitate timely redeterminations based on death and reduce the risk of improper FFS and capitation payments, we reminded States of availability of data sources[80] that interface with the

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[79] §§ 435.912(c)(5)(i) through (iii) (Medicaid); § 457.343 (CHIP) (incorporating § 435.916 and associated Medicaid eligibility renewal and redetermination timeliness standards).

[80] Specifically, the Enumeration Verification System (EVS), State Data Exchange (SDX), Beneficiary and Earnings Data Exchange (BENDEX), State Online Query (SOLQ), State Online Query Internet (SOLQ-I), and Unemployment Insurance Query (UIQ) Type 2.

DMF and may be used to conduct regular, including monthly, matches against enrollment and payment data.[81]

In the final rule titled "Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability" (81 FR 27498) ("2016 Managed Care final rule"), we strengthened managed care plans' responsibilities to protect against overpayments due to enrollees' loss of Medicaid eligibility, such as through death or other changes in circumstances. Revisions made there to § 438.3(c)(2) clarified that MCOs, PIHPs, and PAHPs) may only retain capitation payments for "Medicaid-eligible enrollees," which excludes deceased individuals.[82] That rule also finalized § 438.608(a)(3), which required States to include managed care contract provisions mandating that managed care plans promptly report to SMAs changes in an enrollee's circumstances— specifically death[83] or a change in residence—that may affect the enrollee's eligibility[84] to enable SMAs to promptly redetermine and, when appropriate, terminate eligibility.

The 2016 Managed Care final rule finalized § 438.608(a)(3) because we recognized that managed care plans are a valuable source for beneficiary information, such as current address and date of death.[85] We have encouraged States to increase their reliance on managed care plans for updating beneficiary information to prevent procedural terminations as they resumed normal eligibility operations following the COVID-19 Public Health Emergency (PHE).[86, 87] To mitigate the risk of beneficiaries inappropriately losing Medicaid coverage, we suggested that

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[81] CMS Guidance. "Identifying Deceased Medicaid Enrollees." April 25, 2024. *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AID/guidance-04252024.pdf*.
[82] 81 FR 27537.
[83] § 438.608(a)(3)(ii).
[84] § 438.608(a)(3)(i).
[85] 81 FR 27607.
[86] CMS: "Strategic Approaches to Engaging Managed Care Plans to Maximize Continuity of Coverage as States Resume Normal Eligibility and Enrollment Operations". March 2024 Update. *https://www.medicaid.gov/resources-for-states/downloads/health-plan-strategy.pdf.*
[87] CMCS Informational Bulletin: Ensuring Eligible Children Maintain Medicaid and Children's Health Insurance Program Coverage. December 18, 2023. *https://www.medicaid.gov/federal-policy-guidance/downloads/cib12182023.pdf.*

States consider partnering with managed care plans to verify and update beneficiary contact information, including addresses.[88] We believe many SMAs and managed care plans have sufficient experience and procedures in place to continue reporting and monitoring address changes, consistent with § 438.608(a)(3).

b. Overpayments for Ineligible Enrollees

Various CMS oversight and technical assistance efforts discussed later in this section have demonstrated that changes in residence or death are not always promptly reported to the State, preventing timely redetermination of Medicaid eligibility and, when appropriate, termination of Medicaid coverage. We also reviewed 2024 Medicaid enrollment data and estimated that an average of approximately 1.2 million Americans per month were concurrently enrolled in two or more State Medicaid or CHIP programs.[89] As a result of delays in the identification and reporting of these changes and concurrent enrollments, SMAs may continue making capitation payments for individuals who are no longer Medicaid-eligible and would not reasonably be expected to utilize any Medicaid services due to time and distance.

A 2022 HHS-OIG study on multi-State enrollment found that nearly all States made capitation payments for beneficiaries who were concurrently enrolled in a Medicaid managed care program in two States.[90] The OIG's analysis found that in August 2019 payments were made for 208,254 concurrently-enrolled beneficiaries, generating Medicaid program costs of approximately $72.9 million for capitation payments associated with beneficiaries in one of the two concurrently enrolled States, and in August 2020 payments were made for 327,497 concurrently-enrolled beneficiaries at a cost of $117.1 million. Additionally, the OIG released a report in 2023 summarizing findings from 14 State audits that assessed death data between July

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[88] CMCS presentation of "Strategic Approaches to Engaging Managed Care Plans to Maximize Continuity of Coverage as States Resume Normal Eligibility and Enrollment Operations". March 2024 Update. *https://www.medicaid.gov/resources-for-states/downloads/health-plan-strategy.pdf*.

[89] *https://www.cms.gov/newsroom/press-releases/cms-finds-28-million-americans-potentially-enrolled-two-or-more-medicaid/aca-exchange-plans*.

[90] *Nearly All States Made Capitation Payments for Beneficiaries Who Were Concurrently Enrolled in a Medicaid Managed Care Program in Two States* (HHS-OIG A-05-20-00025). *https://oig.hhs.gov/documents/audit/7881/A-05-20-00025-Complete%20Report.pdf*.

1, 2009 and December 31, 2019 where the OIG identified more than $249 million ($172 million Federal share) in unallowable Medicaid capitation payments that States made to managed care plans on behalf of deceased enrollees across 14 States. Of that, over $41 million (Federal share) remained uncollected as of November 2022.[91, 92, 93, 94, 95]

Our Federal oversight experience has identified a variety of causes for these overpayments, including limited access to death data (especially for deaths that occur outside of the State or territory), reliance on manual processes to terminate eligibility, data interface errors, and claims processing errors. To mitigate these overpayments, some SMAs have developed procedures to obtain death data directly from managed care plans, in accordance § 438.608(a)(3). For example, one State required that managed care plan provider network agreements include a requirement for providers to notify the managed care plan when they learn of an enrollee's death, which the plan then reports to the SMA. To ensure that States are timely made aware of relevant changes, § 438.608(a)(3) requires managed care plans to provide "prompt" reporting of these changes; however, we did not define prompt, nor did we require States to specify how notifications were to be received.

Enhanced reporting alone will not address all causes of these overpayments, which is why we believe clearer recovery provisions are also necessary. In response to reports that managed care plans were retaining capitation payments for deceased individuals, the 2016 Managed Care final rule added § 438.3(c)(2), which establishes that "capitation payments may

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[91] *Multiple States Made Medicaid Capitation Payments to Managed Care Organizations After Enrollees' Deaths* (HHS-OIG A-04-21-09005). https://oig.hhs.gov/documents/audit/7406/A-04-21-09005-Complete%20Report.pdf.
[92] *Colorado made at least $3.8 million (Federal share) in unallowable capitation payments to MCOs on behalf of deceased enrollees between January 2018 and December 2020* (HHS-OIG A-07-21-05132). *https://oig.hhs.gov/documents/audit/10197/A-07-21-05132.pdf*.
[93] *Delaware made unallowable capitation payments totaling at least $4.2 million (over $3.4 million Federal share) to MCOs on behalf of the 409 deceased enrollees between calendar years 2019 and 2021.* (HHS-OIG A-03-22-00205). *https://oig.hhs.gov/documents/audit/9827/A-03-22-00205.pdf*.
[94] *Virginia made unallowable capitation payments totaling at least $21.8 million ($15.7 million Federal share) to MCOs on behalf of 12,054 deceased enrollees between calendar years 2019 and 2021.* (HHS-OIG A-03-22-00203). *https://oig.hhs.gov/documents/audit/6873/A-03-22-00203-Report%20in%20Brief.pdf*.
[95] *Puerto Rico claimed at least $6,979,822 in unallowable Federal Medicaid funds for capitation payments made on behalf of deceased enrollees between April 2018 and September 2020*. (HHS-OIG A-02-21-01005). *https://oig.hhs.gov/documents/audit/6529/A-02-21-01005-Complete%20Report.pdf*.

only be retained by the MCO, PIHP, or PAHP for Medicaid-eligible enrollees". In the preamble, we explained that this limitation was implicit in the existing regulation and that capitation payments are developed based on the services and populations that are authorized for Medicaid coverage and services covered under the contract between the State and managed care plans, and that capitation payments are made for Medicaid-eligible enrollees, which would not include deceased individuals or individuals who are no longer Medicaid-eligible.[96] However, as discussed previously, our audits and data analyses have demonstrated that, in some cases, SMAs continue to improperly pay capitation payments for individuals residing in another State and therefore ineligible for coverage, or were deceased.

c. WFTC Legislation (Pub. L. 119-21) and Capitation Overpayments

Beginning in FY 2026, section 71103 of the WFTC legislation appropriates funding to establish, by October 1, 2029, a system that CMS and States will use to prevent an individual from being simultaneously enrolled under the State plans (or waivers of such plans) of multiple States. States will be required to submit data to the system at least monthly and during each eligibility determination and redetermination. Currently, States continue to be required to participate with the Public Assistance Reporting Information System (PARIS) as required by § 435.945(d). States may elect whether to utilize interstate match results as part of their program integrity activities. To ensure States have more complete address information, sections 71103(a)(2)(B) and 71103(b)(2) of the WFTC legislation amend sections 1932 and 2103(f)(3) of the Act, respectively, to require that, beginning January 1, 2027, each contract under a State plan that a State has with MCOs, primary care case managers (PCCMs), PIHPs, or PAHPs include a provision requiring the entity or plan to promptly transmit to the State any address information received directly from enrollees or verified by the entity or plan directly with the enrollee.

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[96] "It is implicit in the [2016 Final Rule], and we did not propose to change, that capitation payments are developed based on the services and populations that are authorized for Medicaid coverage under the State plan which are covered under the contract between the State and the managed care plan and that capitation payments are made for Medicaid-eligible enrollees. This would not include deceased individuals or individuals who are no longer Medicaid-eligible." 81 FR 27537.

Also, effective January 1, 2027, section 71104 of the WFTC legislation requires that States and the District of Columbia, but not territories, screen all Medicaid enrollees against the Death Master File (DMF) (or a successor system) no less than quarterly to determine whether Medicaid enrollees are deceased. States will be required to treat such information as factual, disenroll deceased beneficiaries with notice of fair hearing rights provided no later than the date of action consistent with 42 CFR part 431 subpart E, and discontinue any payments for medical assistance on the individual's behalf. Prior to the provisions of the WFTC legislation becoming effective on January 1, 2027, pursuant to eligibility verification regulations at §§ 435.945 and 435.952, SMAs are prohibited from acting on DMF data alone and must seek to independently verify a beneficiary's death prior to disenrollment. Once verified, an SMA can terminate coverage immediately, but not retroactively to the date of death and not for items or services furnished prior to death. Section 71104 of the WFTC legislation removes the requirement for additional verification beyond the DMF effective January 1, 2027; however, if an SMA determines that an individual was misidentified as deceased, the SMAs must reenroll the individual immediately and reinstate coverage retroactive to the date of disenrollment.

2. Proposed Policies

a. Standard Contract Requirements Relating to Capitation Payments Retention

Authority for the contracting requirements at § 438.3 is based on section 1903(m)(2)(A)(iii) of the Act (for MCOs) and section 1902(a)(4) of the Act (for PIHPs and PAHPs). Section 1903(m)(2)(A)(iii) of the Act permits Federal matching dollars for State expenditures to a risk-bearing entity for Medicaid services when "such services are provided for the benefit of individuals eligible for benefits under this title in accordance with a contract between the State and the entity under which the prepaid payments to the entity are made on an actuarially sound basis and under which the Secretary must provide prior approval for contracts." We are proposing to amend § 438.3(c)(2) to retain the requirement that capitation payments may only be made by States and retained by MCOs, PIHPs, or PAHPs for Medicaid-eligible

enrollees, while adding provisions that would permit States to recover capitation payments made for certain periods following an individuals' death or out-of-State relocation. We propose to add § 438.3(c)(2)(i) providing that, following the provision of notice of action with fair hearing rights in accordance with §§ 435.917 and 435.918 and part 431 subpart E, a State must recover capitation payments from MCOs, PIHPs, or PAHPs for any payment periods following the death of an enrollee when verified through the DMF, and may recover capitation payments from MCOs, PIHPs, or PAHPs for any payment periods following the date of out-of-State relocation of an individual. We note that these recovery actions would be limited to financial transactions between the State and the managed care plan and would not create any liability for Medicaid beneficiaries. At § 438.3(c)(2)(ii), we propose to add that States would be required to reimburse CMS an amount equal to the Federal share of all capitation payments subject to recovery described in proposed § 438.3(c)(2)(i), taking into account applicable differences in the Federal matching rate(s) applicable to the population, benefit, and Federal Fiscal Year. We note that under § 438.3(c)(2)(ii) States would be required to return the Federal share of capitation payments for any payment periods following the enrollee's death or date of relocation regardless of whether the State elects to recover or require the plan to return the capitation payment. The CHIP regulations at §§ 457.1201(c) and 457.1285 require CHIP managed care plans to comply with all Medicaid managed care rules established within § 438.3(c); therefore, the proposed changes to § 438.3(c)(2), if finalized, would apply to CHIP managed care plans.

This proposal would ensure that States have clear authority to recover capitation payments attributed to individuals who are deceased or who have relocated out-of-State, while the contractual provisions would establish the operational mechanism for implementing those recoveries, regardless of when the State ultimately terminated Medicaid eligibility. This proposal would make clear that existing notice, fair hearing, and eligibility-redetermination requirements would continue to apply before a State may terminate coverage and initiate capitation payment recovery from a managed care plan. As such, States would have to continue

to redetermine eligibility in accordance with requirements at §§ 435.916(d) and 457.343, consider all bases of eligibility before making a determination of ineligibility as required by § 435.916(f), and furnish benefits until the individual is found to be ineligible for Medicaid and provided advance notice, as applicable, as described in §§ 431.211 and 435.930(b). Following completion of notice of action with fair hearing rights and termination of coverage, States would initiate recovery actions from the applicable managed care plan.

Since the 2016 Managed Care final rule, most States have included sufficiently robust contract language to adequately recover capitation payments associated with deceased individuals, but some States have shared with us that they experience challenges recovering capitation payments from managed care plans for enrollees who have relocated out-of-State. When an enrollee has relocated out-of-State, and the State makes a determination of ineligibility and disenrolls the individual after providing advance notice, covered services under the managed care plan's contract should no longer be available to the enrollee because the enrollee is no longer eligible for Medicaid within the original State. Similarly, associated capitation payments would not be consistent with the requirement that capitation rates reflect reasonable, appropriate, and attainable costs under the contract (§ 438.4(a)) because a State may only make payment to a managed care plan for "covered services to Medicaid-eligible individuals in a manner compliant with contractual requirements" (§ 438.3(c)(1)(ii)). Therefore, a payment made for an ineligible enrollee would not be compliant with the contract between the State and the managed care plan. While most SMAs recover capitation overpayments from plans when they are identified, some SMAs are unable to recover such payments because of insufficiently robust managed care contract language.

These challenges are largely related to an inability to identify a date on which to base the recovery. Unlike a date of death, which is recorded in national or State-based sources, such as the Social Security Administration's DMF or States' Departments of Vital Statistics, residential address changes are not routinely tracked and reported. PARIS alerts notify States when a

beneficiary has relocated to another State by matching certain State and Federal data, but such alerts are generated quarterly and only if the individual interacts with certain entities in that new State such as the SMA or the Department of Motor Vehicles. In addition, States have reported challenges using PARIS because they may receive a high volume of false positive alerts,[97] the alerts may be based on delayed data,[98] or the PARIS system does not retain accessible historical data. All SMAs are required to conduct PARIS data matches, but data matching agreements do not prescribe which of the three PARIS matches (the Veterans Administration Match, Department of Defense/Office of Personnel Management Match, and the Interstate Match) SMAs must conduct, nor the frequency with which any match must be conducted.[99]

Prior to initiating capitation payment recoveries based on an out-of-State relocation, States must first define feasible policies and procedures within their managed care contracts for how they will identify when an out-of-State residential change occurs, what documentation sources can be used to establish a relocation date, and how they will resolve cases of disputed residency. The "date of out-of-State relocation" means the date the State determines, consistent with § 435.403 and applicable State residency requirements that the individual ceased to be a resident of the State. States would also need to include clear terms in their managed care contracts that would define how they would determine which capitation payments would be subject to recovery in instances where individuals would not report the timing of their relocation. Further, these policies should align with the Federal requirements regarding State residency at § 435.403(d), and any applicable State-based residency requirements.

SMAs must treat these types of recoveries like all other recovered overpayments resulting from situations other than fraud as outlined generally at § 433.300, which is to refund all

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[97] California Verification Plan (medicaid.gov). *https://www.medicaid.gov/sites/default/files/2021-06/california-verification-plan-final.pdf*.
[98] *https://www.medicaid.gov/sites/default/files/2019-12/new-hampshire-verification-plan-template-final.pdf*.
[99] *Nearly All States Made Capitation Payments for Beneficiaries Who Were Concurrently Enrolled in a Medicaid Managed Care Program in Two States* (HHS-OIG A-05-20-00025). https://oig.hhs.gov/documents/audit/7881/A-05-20-00025-Complete%20Report.pdf.

recoveries, including ones relating to changes in circumstance, to CMS within 1 year from the date of discovery.

We believe adding a new paragraph (i) to § 438.3(c)(2) within the standard contract requirements provisions would clarify States' obligation to recover capitation payments for any payment periods following a beneficiary's date of death and States' ability to recover capitation payments for any payment periods following the date of out-of-State relocation—after making a determination of ineligibility and the provision of notice of action with fair hearing rights—and would ensure that SMAs update their managed care contract terms to clearly specify their intent to recover inappropriate capitation payments. We invite comment on these proposals.

b. Prompt Reporting of Beneficiary Changes in Circumstances (§ 438.608(a)(3))

The provision added by the 2016 Managed Care final rule at § 438.608(a)(3) did not define "prompt" reporting or specify how changes should be reported, and we subsequently observed considerable variation in how States implemented the regulation. To ensure uniformity, we propose to amend § 438.608(a)(3) to require that Medicaid and CHIP managed care plans and Primary Care Case Management (PCCMs) report to a State changes in an enrollee's circumstances (specifically including enrollee deaths and all verified address changes) within 30 calendar days of when a plan receives information about a change that may affect the enrollee's eligibility for or access to services covered under the contract. We also propose to amend § 438.608(a)(3)(i) to require managed care plans and PCCMs to report residence changes if provided by the enrollee or verified directly with the enrollee, including both out-of-State and in-State address changes, which would protect from improper disenrollment. In the 2016 Final Rule, we finalized "§ 438.608(a)(3) so that managed care plans *would* notify the State of changes in the enrollee's residence and death," in an effort to not trigger a required notification by the managed care plan when returned mail is received because the administrative burden on States outweighed the value.[100] At the same time, we acknowledged that managed care plans "have

[100] https://www.federalregister.gov/d/2016-09581/p-1477 (emphasis added).

more direct communication with enrollees than the State and can serve as valuable sources of information relevant to the enrollee's eligibility for Medicaid."[101] In the decade since the 2016 Final Rule, managed care plans have expanded communication from mail and telephone to text messages, email, and member portals and mobile applications. With these additional means of communication, managed care plans and PCCMs are in a better position to verify changes in residence with less burden than the State, thus making notification to the State of the verified change in residence beneficial without being overly burdensome.

The proposed change to § 438.608(a)(3) would also implement sections 71103(a)(2)(B) and 71103(b)(2) of the WFTC legislation, which mandates that States include a provision in their managed care plan and PCCM contracts that requires managed care plans to promptly transmit to the State any address information for Medicaid and CHIP enrollees that is provided to the managed care plan or PCCM directly from, or that the managed care plan or PCCM verified directly with, the enrollee. We propose to amend § 438.608(a)(3) to define this prompt-transmission requirement as requiring transmission within 30 calendar days of when a managed care plan or PCCM receives information about a change in an enrollee's circumstances, which would add clarity and consistency to the implementation of the provisions in section 71103. The CHIP regulations at §§ 457.1201(c) and 457.1285 already require CHIP managed care plans to comply with all Medicaid managed care rules established within §§ 438.3(c) and 438.608, respectively; therefore, no additional regulatory changes would be necessary to implement such changes within CHIP.

In addition, we are proposing to revise § 438.608(a)(3) to require SMAs to define the procedures for prompt notification to the State when changes in an enrollee's circumstances are to be reported, which would ensure that managed care plans and PCCMs report such changes consistently to the appropriate contacts within the SMA or delegated entity. We believe that establishing a uniform timeframe of 30 calendar days would adequately position States and

[101] https://www.federalregister.gov/d/2016-09581/p-1478.

managed care plans and PCCMs to comply with section 71103(a)(2)(B) and 71103(b)(2) of the WFTC legislation, which requires States to include within the managed care contract a requirement that the MCOs, PIHPs, PAHPs, and PCCMs promptly transmit verified address information for enrollees. When a State receives information indicating an enrollee may have moved out-of-State through this process, it must treat such information as a potential change in circumstances and promptly redetermine eligibility in accordance with §§ 435.916(d), 457.343, and 435.952(d). We believe 30 calendar days is a reasonable amount of time for a managed care plan or PCCM to transmit any new address information to the State and would allow States to initiate timely redetermination procedures and potentially prevent transmitting to managed care plans and PCCMs inappropriate capitation payments for enrollees who have a change that may affect their eligibility, or to facilitate enrollment into a new plan for enrollees who continue to be State residents but have moved out of their current plan's service area. However, we are seeking comments on whether 30 calendar days is an appropriate length of time or if the time period should be increased or decreased. In addition, we interpret section 71103(a)(2)(B) of the WFTC legislation's use of "promptly" to apply this reporting rule to enrollees with new address information that differs from prior address information, and we would encourage States to leverage their experience from unwinding the Medicaid continuous enrollment provision at the end of the COVID-19 PHE to inform the development of these procedures and protocols.

Prompt reporting of an enrollee's death by managed care plans would also support provisions included within section 71104 of the WFTC legislation. Beginning January 1, 2027, section 71104 of the WFTC legislation requires States on at least a quarterly basis to review the DMF, or a successor system that provides beneficiary death data, and disenroll any deceased beneficiaries. The WFTC legislation also requires that States reinstate Medicaid coverage for a beneficiary who was erroneously disenrolled. We believe that managed care plans may learn of potential deaths or erroneous disenrollments before State or Federal entities. However, Section 71104 of the WFTC does not permit States to treat death information from managed care plans

as factual, and States will still be required to verify beneficiary death consistent with § 435.952(d).

Section 438.608(a)(3) currently requires States to require managed care plans' prompt reporting to them when the managed care plan receives information about changes in an enrollee's circumstances that may affect the enrollee's eligibility, including change of address and death. We believe that adding a 30-calendar-day timeframe to report out-of-State moves and deceased beneficiary status would strengthen existing requirements and enhance program integrity and eligibility verification in Medicaid.

We propose that these revisions would be applicable for rating periods beginning on or after January 1, 2027. We believe this would also provide sufficient opportunity for States to include these new reporting requirements and recovery provisions in their new or renewed managed care contracts. We invite comment on these proposals.

c. Standard Contract Requirements Relating to Overpayments

We also propose to revise § 438.608(d)(1)(iv) to clarify that the overpayment retention policies specified under § 438.608(d)(1) do not apply to amounts recovered and retained under the False Claims Act or through other Federal or State audits or investigations, including those conducted by Federal agencies, such as CMS, or their contractors. This clarification is intended to ensure that recoveries resulting from fraud, waste, or abuse audits and investigations are treated consistently with existing authorities governing such actions and are not subject to duplicative recovery or return requirements under this section. As stated in the 2016 final rule, "[a]lthough States have the flexibility to implement overpayment retention contract provisions, the policies in the contract would not prohibit the Federal government from retaining the appropriate share of recoveries of overpayments due to their own audits and investigations".[102] We seek comment on this this proposed revision.

[102] https://www.federalregister.gov/d/2016-09581/p-1523.

M. Request for Information on Payment Deductions under 42 CFR 447.10(i)

CMS is issuing this request for information (RFI) to solicit public input on strengthening consent, documentation, and recordkeeping requirements related to payment deductions made under 42 CFR 447.10(i). This regulation governs deductions from certain Medicaid provider payments to make payments to third-parties, including labor unions, on behalf of the provider. CMS is concerned that existing State practices for obtaining and documenting practitioner consent to such deductions may be insufficient to protect practitioners' First Amendment rights and the financial integrity of the Medicaid program. CMS is also considering how to implement a related statutory prohibition enacted under section 71121 of Pub. L 119-21, the WFTC legislation. The information received in response to this RFI could inform potential future agency action.

1. Background

Section 1902(a)(32) of the Act generally prohibits Medicaid payment for care or services furnished to an individual to anyone other than the individual or the provider furnishing the care or services, unless a statutory exception applies. CMS' implementing regulation at § 447.10 identifies the persons to whom State Medicaid payments may be made and the limited circumstances under which payment may be made to others.

Under CMS' current interpretation of section 1902(a)(32) of the Act, as established in a 2022 final rule[103] and pursuant to regulations at § 447.10(i), the payment prohibition in section 1902(a)(32) of the Act does not apply to State payments to third-parties on behalf of individual practitioners for those individual practitioners' health insurance and welfare benefits, skills training, and other benefits customary for employees, in the case of a class of practitioners for which the Medicaid program is the primary source of revenue, if the individual practitioner voluntarily consents to such payments on their behalf.

103 87 FR 29675, May 16, 2022

The preamble to the 2022 final rule noted that "most commenters stated support for the 2021 proposed rule." *See* 87 FR 29675, 29679 (May 16, 2022). But, at the same time, the 2022 final rule also noted that, in response to the 2021 proposed rule,[104] some commenters expressed concerns about bad actors and questionable practices for diverting Medicaid money to unions without providers' express consent, as the agency noted and described in the 2022 final rule, and argued that the consent requirements in § 447.10(i) were insufficient to protect practitioners and the financial integrity of the Medicaid program. *See* 87 FR at 29682-29683, 29686. Some commenters raised concerns about the potential for what they called the practice of "dues skimming," in which a State automatically deducts union dues from a practitioner's Medicaid payment without the practitioner's affirmative consent. *Id*. at 29686. Some commenters cited *Harris v. Quinn*, 573 U.S. 616 (2014), and *Janus v. American Federation of State, County, & Municipal Employees, Council 31*, 585 U.S. 878 (2018), as examples supporting their view that such practices are impermissible and raise First Amendment concerns. *Id*.

Some commenters further described specific practices they viewed as coercive or inconsistent with the consent standard articulated in *Janus*, including so-called "captive audience" meetings, high-pressure tactics associated with union enrollment, and limited ability to disenroll from the union. *Id*. Commenters also expressed concern that finalizing the rule could permit States to divert Medicaid payments to unions and political campaigns. *Id*.

Despite these comments, at the time of the 2022 final rule, CMS believed the requirements at § 447.10(i), particularly the voluntary consent requirement, were sufficient from the Federal perspective and deferred to States to oversee and operationalize this requirement. *See*, *for example*, 87 FR at 29682-29686, 29689. Specifically, we declined to prescribe in regulation a uniform method for obtaining or documenting consent, including a written consent requirement, out of concern that doing so could conflict with State law, and we deferred to States regarding which methods of obtaining and documenting consent are sufficient. *Id*. However,

104 86 FR 41803, August 3, 2021

since the 2022 final rule took effect, CMS has received reports suggesting that these concerns have materialized in practice. In June 2026, CMS sent letters to nine SMAs reminding them of their obligations under § 447.10(i) and of the Supreme Court's holding in *Janus*. In those letters, CMS stated that deductions made without a practitioner's voluntary and affirmative consent are inconsistent with *Janus* and may violate § 447.10. CMS directed States to review their Medicaid payment arrangements involving union dues and requested documentation sufficient to allow CMS to assess compliance.

Although the Supreme Court has not reached the specific question, the First Amendment principles articulated in *Harris* and *Janus* would appear to apply to union deductions from Medicaid payments to homecare workers and would appear to bind States in that context independently of any Federal regulation. Assuming that our understanding of the decisions is correct in this regard, any rule CMS issues with respect to union dues deductions from Medicaid payments must be consistent with those decisions and States' existing constitutional obligations are not optional: that is to say that a State's deduction of union dues from a practitioner's Medicaid payment without the practitioner's clear and affirmative prior and voluntary consent is unconstitutional regardless of whether CMS' regulations separately require it.

We are concerned that current practices in some States may not reliably ensure that consent to the deduction of union dues is obtained in a manner free from coercion or pressure. We note that § 447.10(i) applies broadly to deductions for a range of benefits, not solely union dues, but CMS believes that in the context of union dues, greater regulatory specificity regarding consent, documentation, and recordkeeping may be warranted to ensure voluntary and verifiable consent from practitioners, consistent with applicable First Amendment principles, and to ensure consistent Federal oversight across States.

Separately, section 71121 of the WFTC legislation amended section 1915(c) of the Act by adding a new paragraph (11), which establishes a new HCBS waiver option, available to States beginning July 1, 2028, under which States may provide HCBS to individuals without

requiring them to meet the institutional level-of-care requirement otherwise applicable under section 1915(c). Section 1915(c)(11)(C) of the Act provides that no payments made to carry out that paragraph may be used by a State to make payments to a third-party on behalf of an individual practitioner for benefits such as health insurance, skills training, and other benefits customary for employees, in the case of a class of practitioners for which the Medicaid program is the primary source of revenue. CMS is using this RFI, in part, to inform implementation of this statutory provision.

2. Issues for Public Input

CMS continues to receive reports from practitioners and other stakeholders raising concerns regarding compliance with § 447.10(i) and applicable First Amendment principles , including practitioners reporting that consent to union dues deductions was obtained as a condition of provider enrollment, and practitioners reporting difficulty withdrawing previously given consent. These reports, together with the responses to CMS' June 2026 compliance letters, raise questions regarding whether existing State oversight and implementation of § 447.10(i) consistently ensures compliance with the voluntary consent requirement.

CMS is concerned that deduction of union dues, or other third-party payment under § 447.10(i) may in some circumstances occur without the practitioner's voluntary consent. CMS is considering whether more prescriptive Federal requirements addressing how consent to such deductions must be obtained, documented, and maintained, and how States must demonstrate compliance to CMS, are necessary to ensure the financial integrity of the Medicaid program and to safeguard practitioners' constitutional rights, consistent with *Harris* and *Janus*.

CMS is seeking additional information from States, practitioners, beneficiaries, unions, and other stakeholders to better understand current practices, the scope of the potential problem, and the range of approaches that could address it, including in the context of consumer-directed service programs, where the beneficiary rather than a traditional employer may perform functions relevant to consent and payment.

3. Request for Information

CMS invites public comment on the following questions. Commenters need not respond to every question and are encouraged to provide data, examples, and supporting documentation where available. CMS is not proposing specific regulatory provisions related to this issue in this proposed rule, and nothing in this RFI should be construed as reflecting a predetermined outcome regarding any future policy development.

- What specific practices do States currently use to obtain, verify, and document practitioner consent to deductions under § 447.10(i), including deductions for union dues? How do these practices vary across States and program types (for example, fee-for-service, managed care, consumer-directed HCBS programs)?

- What roles do fiscal intermediaries, financial management services (FMS) entities, and other agents or vendors perform in administering practitioner payments, third-party deductions, and practitioner consent? On whose behalf does each entity act, who receives the Medicaid payment, and in whose name is the payment received? How do these arrangements relate to the payment arrangements addressed in § 447.10(f) and/or (i)?

- How are the respective roles of the State, the employer of record, and the fiscal intermediary defined and enforced? Who is the employer of record for self-directed or independent practitioners? What functions, including data sharing, does the fiscal intermediary perform, and under what authority?

- How do States conduct oversight (including, for example, through audits) of the fiscal intermediaries, or similar agents, as it relates to third-party payments or deductions? What oversight approaches are used, what information is collected, how frequently, and how do States act on the findings? States that have recently audited their fiscal intermediaries are encouraged to describe relevant findings from their most recent audit.

- How are the terms of collective bargaining agreements covering Medicaid practitioners relevant to State administration of deductions and payment of union dues? How

would a State conduct a review, including legal review as appropriate, of such collective bargaining agreements to identify provisions that may conflict with § 447.10 or with *Janus*? What data and information would be collected, and how would a State act on the findings? States that have conducted this type of review are encouraged to describe their most recent process and findings.

- In consumer-directed service models in which the Medicaid beneficiary performs employer-related functions , what unique challenges or considerations arise in ensuring that practitioners' consent to third-party deductions under § 447.10 is voluntary? Are there additional considerations for union dues deductions?

- What processes or safeguards, if any, do States have in place to ensure that practitioners can make voluntary decisions concerning whether or not to agree to union dues deductions without coercion or improper pressure from anyone, whether in favor of or opposed to such deductions? Which individuals or entities may be involved in those interactions, and what barriers or pressures, if any, do practitioners face in exercising their choices?

- What processes or mechanisms, if any, do States have in place to: (1) allow a worker who never consented to dues deductions to avoid paying such dues; and (2) allow a worker who previously consented to union dues deductions to request revocation, subject to any applicable contractual obligations or agreed-upon revocation periods? How are disputes regarding the existence, validity, or effective date of consent or revocation resolved?

- What documentation or recordkeeping requirements would allow CMS to effectively assess State compliance with the voluntary consent requirement in § 447.10(i), without imposing unnecessary administrative burden on States or practitioners?

- What safeguards should CMS consider to ensure that consent is voluntary and not made a condition of provider enrollment or other program participation requirements?

- What data exist, or could reasonably be collected, regarding the frequency, scope, or financial magnitude of deductions made under § 447.10(i) without the voluntary consent required by that provision, or where the existence or validity of consent is disputed?

- What categories of third parties receive payments under § 447.10(i) (such as unions, benefit administrators, or other organizations), and should any future consent, documentation, or recordkeeping requirements distinguish among those categories?

- What implementation questions arise under section 1915(c)(11)(C) of the Act? What guidance, if any, would assist States in identifying payments made to carry out section 1915(c)(11) and the classes of practitioners for which the Medicaid program is the primary source of revenue, and what operational issues should CMS consider?

- What impact, including administrative, operational, or financial, might enhanced Federal consent and documentation requirements have on States, managed care plans, practitioners, fiscal intermediaries, FMS entities, and beneficiaries, particularly in consumer-directed programs?

- Are there alternative regulatory or sub-regulatory approaches that CMS should consider to address the concerns described in this RFI?

- Does the deduction of union dues from Medicaid payments to individual home care workers, with or without adequate consent, positively or negatively affect the financial integrity of the Medicaid program? If so, in what way? What evidence is there of this connection or these effects?

IV. Medicare Advantage and Medicare Part D Proposals

The Balanced Budget Act of 1997 (BBA), Pub. L. 105-33, established a new Part C of the Medicare program, known then as the Medicare+Choice (M+C) program, which became effective in January 1999. As part of the M+C program, the BBA authorized CMS to contract with public or private organizations to offer a variety of health plan options for Medicare beneficiaries. These health plans provide all Medicare Part A and Part B (also known as "Original Medicare," or "Medicare Fee-for-Service (FFS)") benefits, and most offer additional benefits beyond those covered under the Medicare FFS program. The M+C program in Part C of Medicare was renamed the Medicare Advantage (MA) program under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173), enacted in December 2003. The MMA updated and improved the choice of plans for beneficiaries under Part C and changed the way benefits are established and payments are made. As of calendar year 2025, over 34 million individuals receive their Medicare benefits through MA, which represents over half of the total Medicare beneficiary population.[105]

The MMA also established the Medicare Prescription Drug Benefit under Part D, which began providing prescription drug coverage to Medicare beneficiaries in 2006. The Part D program operates through private plan sponsors that contract with CMS, offering coverage either through stand-alone prescription drug plans (PDPs) to supplement Original Medicare, or through Medicare Advantage prescription drug (MA-PD) plans that integrate drug coverage with all other Medicare-covered benefits. The original Part D benefit design included risk-abating mechanisms — including direct subsidy risk corridors, risk adjustment, and Federal reinsurance — enabling CMS to implement a market-based program that maintained affordable premiums over time and promoted high enrollee satisfaction. The Inflation Reduction Act of 2022 (IRA) subsequently made significant structural changes to the Part D benefit, including establishing a hard cap on

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[105] CMS, *CMS Fast Facts, April 2026 Edition,* pg.1, https://data.cms.gov/sites/default/files/2026-04/CMSFastFacts2026_508.pdf.

annual out-of-pocket spending and authorizing the Federal Government to negotiate certain drug prices directly with manufacturers, with those changes being phased in through 2026.

Program integrity is fundamental to the proper administration of both the Part C and Part D programs. While CMS has robust program integrity controls in place, bad actors continue to find the Medicare program a financially lucrative target and use creative tactics to evade detection and adverse consequences. Accordingly, the potential for fraud, waste, and abuse (FWA) is significant, making rigorous oversight of MA organizations and Part D plan sponsors, providers, and suppliers essential to protecting both the Medicare Trust Funds and the beneficiaries who depend on these programs. Compliance oversight of our partners is also important to ensure appropriate expenditures of taxpayer dollars. For example, CMS conducts ongoing oversight of MA organizations and Part D plan sponsors through audits, monitoring, data analysis, and other program integrity activities to ensure compliance with Federal requirements and identify program vulnerabilities. In accordance with 42 CFR 422.504(h)(1) and 423.505(h)(1), MA organizations, Part D plan sponsors, and their employees, governing body members, and first-tier, downstream, and related entities agree to comply with Federal laws and regulations designed to prevent or ameliorate fraud, waste, and abuse. Through these oversight activities and its experience administering the Part C and Part D programs, CMS has identified opportunities to strengthen existing regulatory requirements to improve accountability and clarify program integrity standards.

A. Overview of Proposed Policies

In this proposed rule, CMS proposes to expand its implementation of the requirements set forth in Sections 2008 and 6063 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, Pub. L. No. 115-271 (2018), previously implemented through the Contract Year 2022 Medicare Advantage and Part D Final Rule, which appeared in the **Federal Register** on January 19, 2021 (86 FR 5864). CMS further relies on the authority provided under section 1857(e)(1) of the Act, which authorizes the

Secretary to include in an MA organization contract such other terms and conditions as the Secretary finds necessary and appropriate. In addition, pursuant to section 1856(b)(1) of the Act, the Secretary may establish, through regulation, other standards for MA organizations necessary to carry out the program. Pursuant to section 1860D-12(b)(3) of the Act, the provisions of section 1857 — including section 1857(e)(1) — apply to Part D plan sponsor contracts in the same manner as they apply to MA organizations. Specifically, CMS relies on these provisions for its proposed expansion of mandatory fraud, waste, and abuse reporting requirements, and for the requirement to report all payment suspensions based on credible allegations of fraud. Under existing requirements at §§ 422.503(b)(4)(vi)(G)(*4*)-(*7*) and 423.504(b)(4)(vi)(G)(*4*)-(*7*), MA organizations and Part D plan sponsors are required, in accordance with §§ 422.503(b)(4)(vi)(G)(*5*) and 423.504(b)(4)(vi)(G)(*5*), to report information concerning: (1) any payment suspensions implemented by a plan sponsor, pending the investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary's implementation under section 1862(o)(1) of the Act; and (2) investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan sponsor related to the inappropriate prescribing of opioids to the Health Plan Management System (HPMS) Fraud, Waste, and Abuse (FWA) Reporting Module. While CMS currently encourages plan sponsors to report referrals of substantiated or suspicious fraud, waste, or abuse to CMS, it is not mandatory. CMS is now proposing to make referrals of substantiated or suspicious fraud, waste, and abuse a mandatory reporting requirement, to expand plan sponsors' required reporting of payment suspensions of credible allegations of fraud against pharmacies to other provider and supplier types, and to add the definition of "credible allegation of fraud" to § 422.500 to ensure the Medicare Advantage program requirements align with the current definitions §§ 405.370, 423.4, and 455.2. If finalized as proposed, the requirements for mandatory reporting of fraud, waste and abuse would become effective 60 days after publication of the final rule and would be applicable January 1,

2028.

In addition, CMS is proposing changes to the regulation in Part 422 governing the MA RADV Program. These proposals include: applying extrapolation to plan year audits for payment year 2018 forward; requiring MA organizations to remit improper payments based on RADV audits, in a manner specified by CMS; and allowing MA organizations to request a hardship exception, as prescribed by CMS, if they cannot submit medical records timely as required.

B. Mandatory Reporting of Fraud, Waste, and Abuse

1. Introduction

All MA organizations (including MA organizations offering prescription drug plans (MA-PD plans)) and standalone Part D plan sponsors (collectively referred to herein as "plan sponsors") are required to adopt and implement effective compliance programs to oversee provider networks, benefits, and payments. Compliance programs must include measures that prevent, detect, and correct non-compliance with CMS' program requirements, as well as measures that prevent, detect, and correct fraud, waste, and abuse.[106] As part of these requirements, plan sponsors must establish and implement procedures and systems for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with CMS requirements.

An important part of plan sponsors' fraud, waste, and abuse initiatives involves sharing potential leads, trends, or schemes resulting from the plan sponsors' own data analytics and investigative findings through referrals to CMS, which helps accomplish the following objectives:

- Enables CMS to perform data analysis to identify fraud schemes;

[106] *See* Section 1860D-4(c)(1)(D) of the Act and §§ 422.503(b)(4)(vi) and 423.504(b)(4)(vi).

- Facilitates and increases transparency among CMS and plan sponsors through the exchange of information;
- Provides information and education to plan sponsors on potential fraud, waste, and abuse issues, enabling plan sponsors to investigate and take action based on such data;
- Improves fraud detection across the Medicare program, allowing for increased recovery of taxpayer dollars and enrollee expenditures (for example, premiums, co-insurance, other plan cost-sharing);
- Provides more effective support, including fraud leads, to plan sponsors and law enforcement; and
- Increases beneficiary safety through increased oversight measures.

In this proposed rule, CMS proposes to expand upon the existing requirements in sections 2008 and 6063 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act that CMS previously addressed in the Contract Year 2022 Medicare Advantage and Part D Final Rule (referred to as the "January 2021 final rule" (CMS-4190-F2)). Beginning January 1, 2022, the requirements finalized in the January 2021 Final Rule allowed CMS and plan sponsors to share data and information regarding unscrupulous actors, take swift action based on such data and information, and achieve enhanced outcomes in our efforts to fight the opioid crisis. In addition, the January 2021 Final Rule paved the way for more effective referrals to law enforcement based on plan sponsor reporting, ultimately resulting in reduced beneficiary harm and greater savings for the Medicare program.

2. SUPPORT Act Sections 2008 and 6063

The SUPPORT Act was signed into law on October 24, 2018, and amended sections 1860D–12(b) and 1859 of the Act to alleviate the nationwide opioid crisis by: (1) reducing the abuse and supply of opioids; (2) helping individuals recover from opioid addiction and supporting the families of these persons; and (3) establishing innovative and long-term solutions

to the crisis. Part of CMS' role in overseeing the Medicare program is to ensure that payments are made correctly and that fraud, waste, and abuse is stemmed; failing to do so endangers the Trust Funds and can result in harm to beneficiaries. For example, a practitioner engaging in abusive behavior by prescribing unnecessary opioids to Medicare patients poses a threat to the health and safety of the affected beneficiaries, and Trust Fund dollars paid for drugs that were not needed. As a result, several of the SUPPORT Act provisions addressed important program integrity and payment safeguard topics.

Sections 2008 and 6063 of the SUPPORT Act authorized plan sponsors to suspend payments to pharmacies based on credible allegations of fraud; required plan sponsors to report such payment suspensions to CMS through a secure program integrity portal; and clarified that a fraud hotline tip, without further evidence, does not constitute sufficient evidence of a credible allegation of fraud. The SUPPORT Act also required CMS to establish a secure program integrity portal to facilitate referrals and data sharing related to fraud, waste, and abuse among CMS, plan sponsors, and Medicare program integrity contractors; define, through rulemaking, substantiated or suspicious activities of fraud, waste, or abuse and inappropriate opioid prescribing; establish reporting requirements for plan sponsors related to fraud investigations and inappropriate opioid prescribing; and provide plan sponsors with regular program integrity information and fraud, waste, and abuse trend reports.

3. CMS Actions and Contract Year 2022 Medicare Advantage and Part D Final Rule (January 2021 Final Rule)

In accordance with the requirements of sections 2008 and 6063 of the SUPPORT Act, CMS established a secure web-based program integrity portal for plan sponsor reporting in the HPMS FWA Reporting Module in the Contract Year 2022 Medicare Advantage and Part D Final Rule (January 2021 Final Rule) (86 FR 5864). Since January 1, 2022, under §§ 422.503(b)(4)(vi)(G)(*4*)-(*5*) and 423.504(b)(4)(vi)(G)(*4*)-(*5*) and the associated timelines for reporting found at §§ 422.503(b)(4)(vi)(G)(*6*) and 423.504(b)(4)(vi)(G)(*6*), plan sponsors must

report to CMS: (1) payment suspensions pending investigations of credible allegations of fraud by pharmacies; and (2) information concerning investigations, credible evidence of suspicious activities of a provider (including a prescriber) or supplier related to the inappropriate prescribing of opioids, and other actions taken by the plan sponsor related to the inappropriate prescribing of opioids. In addition, under §§ 422.503(b)(4)(vi)(G)(*3*) and 423.504(b)(4)(vi)(G)(*3*), plan sponsors should have procedures to voluntarily self-report potential fraud or misconduct in the MA or Part D programs to CMS. When plan sponsors choose to report a referral of substantiated or suspicious activities of a provider or supplier related to fraud, waste, or abuse, they must also use the HPMS FWA Reporting Module to do so in accordance with §§ 422.503(b)(4)(vi)(G)(*5*) and 423.504(b)(4)(vi)(G)(*5*). In the January 2021 Final Rule, CMS also defined (or, for "credible allegation of fraud" in § 405.370, updated the definition for) the following terms:

- "Substantiated or Suspicious Activities of Fraud, Waste, or Abuse" (§ 422.500 and 423.4)
- "Inappropriate Prescribing" (§§ 422.500 and 423.4)
- "Credible Allegation of Fraud" (§§ 405.370, 423.4, and 455.2)
- "Fraud Hotline Tip" (§§ 405.370, 422.500, 423.4, and 455.2)

Lastly, in accordance with §§ 422.503(b)(4)(vi)(G)(*7*) and 423.504(b)(4)(vi)(G)(*7*), CMS provides a quarterly report to plan sponsors of data or information reported under these provisions.

4. Proposals to Strengthen the Reporting Requirements

In its July 2018 report, "The MEDIC Produced Some Positive Results but More Could be Done to Enhance its Effectiveness,"[107] the HHS-OIG recommended that CMS require plan

[107] Department of Health and Human Service, Office of the Inspector General, "The MEDIC Produced Some Positive Results but More Could be Done to Enhance its Effectiveness" (2018), https://oig.hhs.gov/reports/all/2018/the-medic-produced-some-positive-results-but-more-could-be-done-to-enhance-its-effectiveness/.

sponsors to report Part C and Part D fraud and abuse incidents and the corrective actions taken to a centralized system. The OIG added that requiring plan sponsors to use some centralized system to report suspect providers and pharmacies, investigative information, and corrective actions would provide the Medicare Drug Integrity Contractor (MEDIC) and plan sponsors with valuable information to use in their fraud-fighting efforts. The report also stated this would enhance CMS oversight by providing transparency into the plan sponsors' efforts to protect the program from fraud, waste, and abuse.

The OIG recommendation for CMS to require plan sponsors to report Part C and Part D fraud and abuse incidents and the corrective actions taken to address them to a centralized system has remained an open recommendation since the release of the 2018 report, which means that it is considered by the OIG to be unimplemented. Through the authority given in the SUPPORT Act, CMS has taken steps to address the OIG's recommendations to require plan sponsor reporting, establish a centralized reporting system, and increase transparency in the Medicare Part C and Part D program, measures that are outlined in the current regulations for plan sponsors in §§ 422.503(b)(4)(vi)(G)(*4*) though (*6*) and 423.504(b)(4)(vi)(G)(*4*) though (*6*). But while plan sponsors are required to report certain information to CMS under these regulations, plan sponsors retain discretion to report referrals involving substantiated or suspicious activities of a provider (including a prescriber) or supplier related to fraud, waste, and abuse. In fact, CMS has found that less than half (46 percent in CY 2025) of Medicare Part C and Part D plan contracts reported referrals of substantiated or suspicious fraud, waste, and abuse to CMS. Additionally, while plan sponsors are required to report payment suspensions based on credible allegations of fraud by pharmacies, only 19 percent of Medicare Part C and Part D plan contracts reported any payment suspensions based on credible allegations of fraud to CMS in CY 2025, including both pharmacies and other provider and supplier types.[108] The low reporting

[108] Plan sponsors that do not report referrals or payment suspensions as required to the HPMS FWA Reporting Module may be subject to a CMS audit or compliance action in accordance with §§ 422.504(e)(2) and 423.505(e)(2) and sections 1857(c) and (h) of the Act, respectively.

rates for these two measures suggest there may be a significant number of additional substantiated or suspicious FWA referrals and payment suspensions for other provider or supplier types that are not being reported to CMS, severely limiting CMS' visibility into potential program integrity risks.

CMS believes that maximized reporting is essential to the oversight of the Medicare Part C and Part D programs, as this information is valuable to CMS and assists with investigations, referrals to law enforcement, and trend monitoring. In addition, more stringent reporting requirements would allow CMS to appropriately share the more robust data on referred providers or suppliers with other MA organizations and Part D contracts on a quarterly basis to assist in their own internal fraud, waste, and abuse efforts. Data transparency and information sharing with our partners are at the core of CMS' strategy to crush fraud. Therefore, CMS is proposing to: 1) require all plan sponsors to report all referrals of substantiated or suspicious fraud, waste, and abuse to CMS through the HPMS FWA Reporting Module; and 2) expand plan sponsor reporting of payment suspensions based on credible allegations of fraud by pharmacies to all provider and supplier types. As CMS is proposing to expand the reporting of payment suspensions for credible allegations of fraud beyond pharmacies, CMS is also proposing to add the definition of "credible allegation of fraud" to § 422.500, to ensure the Medicare Part C program requirements align with the current definitions at §§ 405.370, 423.4, and 455.2.

CMS is also proposing to specify that plan sponsors must report any inappropriate opioid prescribing to CMS no later than 30 days after the closing of the previous quarter. Based on our Part C and Part D program integrity audits and questions submitted to the HPMS FWA Reporting Module mailbox, we have determined that plan sponsors have some misperception regarding the expectations for the requirements at §§ 422.503(b)(4)(vi)(G)(*6*)(*ii*) and 423.504(b)(4)(vi)(G)(*6*)(*ii*). When the HPMS FWA Reporting Module was first launched, consistent with these regulations, plan sponsors were required to submit referrals related to inappropriate opioid prescribing, and, at their discretion, submit separate referrals involving

substantiated or suspicious fraud, waste, and abuse. Feedback from plan sponsors indicated that these requirements imposed a burden because referrals related to inappropriate opioid prescribing were often part of a larger referral of substantiated or suspicious fraud, waste, and abuse. As such, CMS updated the HPMS FWA Reporting Module, beginning November 17, 2023,[109] to include a new question regarding referrals for substantiated or suspicious fraud, waste, and abuse. The new question allows plan sponsors to indicate whether the referral relates to the inappropriate prescribing of opioids. If the plan sponsor indicates that a referral is related to the inappropriate prescribing of opioids, the system will automatically mark the contracts as having submitted a referral of inappropriate prescribing of opioids for that quarter and no further action is needed by the plan sponsor. But when a plan sponsor has not submitted a referral of substantiated or suspicious fraud, waste, and abuse related to inappropriate prescribing of opioids, the system requires the plan sponsor to submit a "No" response as a quarterly attestation to satisfy the quarterly reporting requirement. Ultimately, this system action is meant to ensure (and allow CMS to ensure) that plan sponsors are actively aware they are submitting no referrals of inappropriate prescribing for a given quarter. However, to best ensure that plan sponsors report any inappropriate opioid prescribing to CMS no later than 30 days after the closing of the previous quarter, CMS is also proposing to specify this submission requirement.

Consistent with the previous discussion, we are also proposing the following regulatory provisions to implement mandatory reporting of referrals of substantiated or suspicious fraud, waste, and abuse and to expand the reporting of payment suspensions based on credible allegations of fraud. Our proposals modify or supplement existing regulations, while others establish new regulatory subparagraphs altogether. Regulations related to Part C are addressed in 42 CFR part 422; those pertaining to Part D are addressed in 42 CFR part 423.

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[109] November 3, 2023, HPMS Memo titled "Health Plan Management System (HPMS) Program Integrity (PI) Portal for Fraud, Waste, and Abuse (FWA) Reporting Module Enhancements."

CMS is also proposing to add the definition of "credible allegation of fraud" to § 422.500. This term is already defined in §§ 405.370, 423.4, and 455.2. Consistent with those regulations, we propose "credible allegation of fraud" under § 422.500 to mean an allegation from any source, including but not limited to any of the following: (1) fraud hotline tips verified by further evidence; (2) claims data mining; and (3) patterns identified thorough provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability.

Current §§ 422.503(b)(4)(vi)(G)(*3*) and 423.504(b)(4)(vi)(G)(*3*) state that plan sponsors should have procedures to voluntarily self-report potential fraud or misconduct related to MA organizations and Part D programs, respectively, to CMS or its designee. To mitigate terminology confusion among plan sponsors and align regulatory language with what is currently reported to CMS via the HPMS FWA Reporting Module, CMS proposes to remove the existing language at §§ 422.503(b)(4)(vi)(G)(*3*) and 423.504(b)(4)(vi)(G)(*3*). The existing language at §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*), which require reporting of payment suspensions and credible evidence of suspicious activities, would be redesignated as §§ 422.503(b)(4)(vi)(G)(*3*) and 423.504(b)(4)(vi)(G)(*3*), respectively. CMS proposes to modify subparagraph (i) to the redesignated §§ 422.503(b)(4)(vi)(G)(*3*) and 423.504(b)(4)(vi)(G)(*3*) to remove the reference to "by a pharmacy," to allow for and require reporting for all payment suspensions implemented based on credible allegations of fraud. In addition, CMS proposes to add a subparagraph (iii) to the redesignated §§ 422.503(b)(4)(vi)(G)(*3*) and 423.504(b)(4)(vi)(G)(*3*) to include the new mandatory requirement for plan sponsors to report any referrals of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste, and abuse for initiating or assisting investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners.

Specifically, the redesignated §§ 422.503(b)(4)(vi)(G)(*3*) and 423.504(b)(4)(vi)(G)(*3*) would state that the MA organization or Part D plan sponsor, respectively, "must have procedures to identify, and must report to CMS or its designee, any of the following in the manner described in paragraphs (b)(4)(vi)(G)(*3*) and (*4*) of this section," and would read and require as follows in subsections (*i*) through (*iii*):

- Any payment suspension implemented by a MA organization or Part D plan sponsor, pending investigation of credible allegations of fraud, which must be implemented in the same manner as the Secretary's requirement under section 1862(o)(1) of the Act.
- Any information concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the MA organization or Part D plan sponsor related to the inappropriate prescribing of opioids.
- Any substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste, or abuse for initiating or assisting investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners.

Secondly, we propose to redesignate §§ 422.503(b)(4)(vi)(G)(*5*) and 423.504(b)(4)(vi)(G)(*5*), which currently describe the location where the data must be submitted, as §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*), respectively, and modify the language of the redesignated provisions by replacing the individual reporting requirements language in the current §§ 422.503(b)(4)(vi)(G)(*5*) and 423.504(b)(4)(vi)(G)(*5*) with citation to the associated reporting requirements in redesignated §§ 422.503(b)(4)(vi)(G)(*3*) and 423.504(b)(4)(vi)(G)(*3*) described earlier. Because referrals of substantiated or suspicious fraud, waste, and abuse would be mandatory reporting requirements, there would be no need to distinguish between which referrals were required and which were voluntary. Removing this language streamlines the citation and makes it clearer for the reader. In addition, we propose to redesignate §§ 422.503(b)(4)(vi)(G)(*6*)(*i*)-(*ii*) and 423.504(b)(4)(vi)(G)(*6*)(*i*)-(*ii*), which require

plan sponsors to report information within certain timeframes, as subsections (*i*) and (*ii*) at §§422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*), respectively. The reporting timeframes at §§ 422.503(b)(4)(vi)(G)(*6*)(*i*)-(*ii*) and 423.504(b)(4)(vi)(G)(*6*)(*i*)-(*ii*) are identified separately in the current regulation; however, for clarity, CMS believes it is logical to instead list the timeframes plan sponsors must report the data within as subsections to §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*), which specify where the data must be submitted. We also propose the following in these redesignated provisions: correcting a missing space in "7day" at § 423.504(b)(4)(vi)(G)(*6*)(*i*); updating referenced citations to align with the proposed redesignations and revisions; updating references from "plan" to "MA organization" or "Part D plan sponsor," as applicable, to ensure consistency with the existing terminology used at §§ 422.503 and 423.504; adding the timeframe for reporting referrals of substantiated or suspicious fraud, waste, and abuse to match the existing timeframes for reporting inappropriate opioid prescribing; and removing information regarding the first data reporting period, as it is now outdated. Specifically, these proposed changes at redesignated §§ 422.503(b)(4)(vi)(G)(*4*) and 423.504(b)(4)(vi)(G)(*4*) would state that the MA organization or Part D plan sponsor, respectively, "must submit data, as specified in this section, in the program integrity portal when reporting the referrals described in paragraph (b)(4)(vi)(G)(*3*) of this section. The data categories, as applicable, include referral information and actions taken by the "MA organization," or "Part D plan sponsor," as appropriate, "on the referral." In addition, §§ 422.503(b)(4)(vi)(G)(*4*)(*i*)-(*ii*) and 423.504(b)(4)(vi)(G)(*4*)(*i*)-(*ii*) would read as follows:

- The MA organization or Part D plan sponsor is required to notify the Secretary, or the Secretary's designee, of a payment suspension described in paragraph (b)(4)(vi)(G)(*3*)(*i*) of this section 7 days prior to implementation of the payment suspension. The MA organization or Part D plan sponsor may request an exception to the 7-day prior notification to the Secretary, or the Secretary's designee, if circumstances warrant a reduced reporting time frame, such as potential beneficiary harm.

- The MA organization or Part D plan sponsor is required to submit the information described in paragraph (b)(4)(vi)(G)(*3*)(*ii*) and (*iii*) of this section, or the absence of any information, no later than January 30, April 30, July 30, and October 30 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30.

Lastly, we propose to redesignate §§ 422.503(b)(4)(vi)(G)(*7*)(*i*) and 423.504(b)(4)(vi)(G)(*7*)(*i*), which refer to CMS' requirements for providing plan sponsors a data report, as §§ 422.503(b)(4)(vi)(G)(*5*) and 423.504(b)(4)(vi)(G)(*5*), respectively. In addition, we propose to modify the language in redesignated (b)(4)(vi)(G)(*5*) to update the citation reference. We also propose to redesignate §§ 422.503(b)(4)(vi)(G)(*7*)(*ii*) and (*iii*) and 423.504(b)(4)(vi)(G)(*7*)(*ii*) and (*iii*), which describe requirements of the data report, as §§ 422.503(b)(4)(vi)(G)(*5*)(*i*) and (*ii*) and 423.504(b)(4)(vi)(G)(*5*)(*i*) and (*ii*). In addition, we propose to delete the existing subparagraph (iv) as it is no longer relevant. The language at §§ 422.503(b)(4)(vi)(G)(*5*) and 423.504(b)(4)(vi)(G)(*5*) would state that CMS provides MA organizations or Part D plan sponsors, respectively, "with data report(s) or links to the information described in paragraphs (b)(4)(vi)(G)(*3*)(*i*) through (*iii*) of this section no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30." In addition, (*i*) and (*ii*) of the redesignated regulation would read:

- Include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders.

- Are anonymized information submitted by MA organizations or Part D plan sponsors without identifying the source of such information.

C. Medicare Advantage Risk Adjustment Data Validation (RADV) Reforms

In this proposed rule, we discuss the proposed changes to the regulations in Part 422

governing the MA program. We are proposing to reissue provisions concerning the use of extrapolation in RADV audits and our decision not to apply an FFS Adjuster when calculating RADV overpayments due to a U.S. District Court for the Northern District of Texas vacating, for procedural reasons, similar provisions of a CMS final rule published February 1, 2023.[110] We are also proposing new provisions related to improvements to the hardship exception process in RADV audits.

The following is a summary of the proposed changes included in this proposed rule:

- We propose to reissue § 422.300 as it currently appears including the phrase "collection of improper payments."

- We propose to reissue and amend § 422.310(e) Validation of risk adjustment data, to: (1) apply extrapolation in RADV audits for payment year 2018 and subsequent payment years, using CMS published payment error calculation methodologies; (2) require MA organizations to remit improper payments identified through RADV audits, in a manner specified by CMS and consistent with applicable HHS and CMS overpayment collection regulations; and (3) allow MA organizations to request a hardship exception, subject to CMS' discretionary review, when they are unable to timely submit medical records as required.

- We propose to reissue § 422.311 RADV Audit Dispute and Appeal Processes, to apply revised audit requirements and methodologies.

1. Introduction

a. General Overview of Risk Adjustment Payments in the MA Program

Section 1853(a)(1)(C) of the Act requires that CMS adjust payments made to MA organizations based on risk. Risk adjustment ensures that CMS is able to make appropriate and accurate payments for enrollees with differences in costs. Making accurate payments to MA organizations also ensures we are safeguarding Federal taxpayer dollars.

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[110] *Humana Inc. v. Becerra,* 801 F.Supp.3d 624 (N.D. Tex. 2025), *appeal docketed sub nom. Humana Inc. v. Kennedy*, No. 25-11082 (5th Cir. Nov. 21, 2025).

The risk adjustment model employed to adjust MA payments is known as the CMS Hierarchical Condition Category (CMS-HCC) model. This model functions by categorizing the International Classification of Disease, Clinical Modification (ICD-CM)[111] diagnosis codes into disease groups called Hierarchical Condition Categories, or HCCs. Each HCC includes diagnosis codes that are related clinically and have similar cost implications. MA enrollee HCCs are assigned based on data submitted to CMS by MA organizations. The HCCs contribute to an enrollee's risk score, which is used to adjust a base payment rate. Essentially, the higher the risk score for an enrollee, the higher the expected health care cost for the enrollee and the greater payment that is received by the MA organization.

The CMS-HCC model was first used for payment in 2004 and has been recalibrated numerous times since then. When CMS recalibrates the CMS-HCC risk adjustment model, it uses data from Medicare FFS claims, using diagnoses in one year to predict the following year's expenditures. Claims data from beneficiaries enrolled in the Medicare FFS program are used to calibrate the CMS-HCC model, which produces a set of coefficients that represent the marginal (additional) cost of each medical condition and demographic factor reported for a given beneficiary. (For additional information, see the Medicare Managed Care Manual, CMS Pub. 100-16, Chapter 7, section 70.1.)[112] These coefficients are then divided by the average predicted expenditure for the population, also known as the model denominator, to generate relative factors that reflect expected costs relative to the average cost FFS beneficiary. Each beneficiary's relative factors are added together to yield a risk score for that beneficiary that is used to adjust the base payment rate for that beneficiary.

For a diagnosis to be acceptable for risk adjustment, it must be from an acceptable provider type (that is, hospital inpatient facilities, hospital outpatient facilities, or physicians),

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[111] The ICD-CM is a modification of the ICD, authorized by the World Health Organization, used as a source for diagnosis codes in the United States. The ICD-CM has been adopted by the Secretary as the standard medical data code set. *See* 45 CFR 162.1002.

[112] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c07.pdf.

coded in accordance with ICD-CM coding guidelines, result from a face-to-face visit, and be documented in a medical record, and MA organizations are required to ensure the accuracy and integrity of risk adjustment data submitted to CMS.[113]

CMS uses diagnostic information submitted by MA organizations to calculate risk scores. MA organizations are required to submit data that is accurate, complete, and truthful to the best of their knowledge. CMS pays prospectively and issues final payment through a reconciliation run. As such, the diagnosis data the MA organizations submit do not undergo CMS validation prior to use for risk score calculation and payment. CMS validation audits occur post payment reconciliation. CMS conducts post-payment audits of MA organization-submitted diagnosis data from a selection of MA organizations for specific payment years to ensure that the diagnoses they submitted are supported by their enrollees' medical records. These audits are called contract-specific MA RADV program audits. While RADV audits are intended to identify improper risk adjustment payments, they are not specifically designed to detect fraud,[114] nor are they intended to identify all improper diagnosis submissions made by MA organizations for risk adjustment payment.[115]

b. Purpose and Description of Contract-Specific RADV Audits

The improper payment measurements conducted each year by CMS that are included in the HHS Agency Financial Report, as well as audits conducted by the HHS-OIG, have demonstrated that the MA program is at high risk of improper payments. In Fiscal Year (FY)

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[113] Medicare Managed Care Manual, CMS Pub. L. 100-16, chapter 7, section 40 (2014).

[114] For example, the Department of Justice is responsible for pursuing potential violations of the False Claims Act, which includes certain elements of knowledge.

[115] CMS contract-specific RADV audits focus on specific MA organization contracts to determine and recoup improper payments. The HHS-OIG also undertakes audits of MA organizations, similar to RADV audits, as part of its oversight functions. CMS can collect the improper payments identified during those HHS-OIG audits, including the extrapolated amounts calculated by the OIG. CMS also oversees the Part C Improper Payment Measurement, previously referred to as "national RADV," to determine a program-wide improper payment rate as required by the Payment Integrity Information Act of 2019 (Pub. L. 116-117). In addition to risk adjustment oversight conducted by CMS, HHS also oversees HHS-RADV, which was created by the Affordable Care Act (Pub. L. 111-148 and Pub. L. 111-152) to strengthen the integrity of the Affordable Care Act Marketplace by validating the accuracy of data submitted by issuers that is used to calculate the amount of funds transferred to insurers based on the actuarial risks of the individuals they enroll. Neither the Part C Improper Payment Measurement nor the HHS-RADV programs are subject to the provisions outlined in this proposed rule.

2025 (based on calendar year 2023 payments), we estimated that CMS made over $21 billion in Part C overpayments, a figure representing over 5 percent of total Part C payments.[116] The HHS-OIG has also released several reports over the past few years that demonstrate a high risk of improper payments in the MA program,[117] and for several years has identified the MA program as one of the top management and performance challenges facing HHS due to the high amount of improper payments.[118] The Medicare program, including MA, has also been identified by the Government Accountability Office (GAO) as a high-risk program due to the risk of substantial improper payments and actions were needed to reduce these risks.[119]

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[116] HHS, FY 2025 HHS Agency Financial Report, pg. 154, https://www.hhs.gov/sites/default/files/fy-2025-hhs-agency-financial-report.pdf. As identified in this report, CMS made over $23 billion in total Part C improper payments. The improper payment measurement for the MA program in FY 2025 included both overpayments ($21 billion) and underpayments ($2 billion).

[117] For example, see reports: CMS Potentially Overpaid Medicare Advantage Organizations $462 Million Based on Certain Unsupported Acute Stroke Diagnosis Codes, Issued on May 28, 2026, https://oig.hhs.gov/reports/all/2026/cms-potentially-overpaid-medicare-advantage-organizations-462-million-based-on-certain-unsupported-acute-stroke-diagnosis-codes/;
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Priority Health (Contract H2320) Submitted to CMS, Issued March 31, 2026, https://oig.hhs.gov/reports/all/2026/medicare-advantage-compliance-audit-of-specific-diagnosis-codes-that-priority-health-contract-h2320-submitted-to-cms/;
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Gateway Health Plan, Inc., (Contract H5932) Submitted to CMS, Issued March 12, 2026, https://oig.hhs.gov/reports/all/2026/medicare-advantage-compliance-audit-of-specific-diagnosis-codes-that-gateway-health-plan-inc-contract-h5932-submitted-to-cms/;
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross and Blue Shield of Alabama (Contract H0104) Submitted to CMS, Issued March 10, 2026, https://oig.hhs.gov/reports/all/2026/medicare-advantage-compliance-audit-of-specific-diagnosis-codes-that-blue-cross-and-blue-shield-of-alabama-contract-h0104-submitted-to-cms/;
Medicare Advantage Compliance Audit of Specific Diagnosis Codes Humana Health Benefit of Louisiana (Contract H1951) Submitted to CMS, Issued December 18, 2025, https://oig.hhs.gov/reports/all/2025/medicare-advantage-compliance-audit-of-specific-diagnosis-codes-humana-health-benefit-of-louisiana-contract-h1951-submitted-to-cms/;
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health and Life Insurance Company (Contract H1608) Submitted to CMS, Issued June 3, 2025, https://oig.hhs.gov/reports/all/2025/medicare-advantage-compliance-audit-of-specific-diagnosis-codes-that-coventry-health-and-life-insurance-company-contract-h1608-submitted-to-cms/.https://oig.hhs.gov/oas/reports/region7/71901187.asphttps://oig.hhs.gov/oas/reports/region2/21801028.asphttps://oig.hhs.gov/oas/reports/region3/31900001.asphttps://oig.hhs.gov/oas/reports/region2/22001009.asphttps://oig.hhs.gov/oas/reports/region7/71701169.asphttps://oig.hhs.gov/oas/reports/region7/71601165.asp

118 For example, see OIG, 2024 Top Management and Performance Challenges Facing HHS, `https://oig.hhs.gov/reports-and-publications/top-challenges/2021/2021-tmc.pdf` https://oig.hhs.gov/documents/tmc/10057/2024%20Top%20Management%20and%20Performance%20Challenges%20Facing%20HHS.pdf

[119] For example, see reports: GAO, *Medicare Program & Improper Payments,* https://www.gao.gov/highrisk/medicare-program-improper-payments;
Actions Needed to Reduce Improper Payment and Fraud Risks in VA Community Care and Medicare Advantage, GAO-26-107946 (2026), https://www.gao.gov/products/gao-26-107946.

RADV audits are our main corrective action for overpayments made to MA organizations when there is a lack of documentation in the medical record to support the diagnoses reported for risk adjustment. We select MA organizations for RADV audits using a risk-based approach that focuses on HCCs that are more likely to be in error as identified by prior RADV audits, Part C Improper Payment Measurements, OIG findings, and other vulnerability analyses. RADV audits occur after the final risk adjustment data submission deadline for the MA contract year and after CMS calculates final payments, as described at § 422.310(g).[120]

RADV audits are intended to confirm that risk adjustment conditions (that is, diagnoses that map to HCCs) reported by MA organizations are supported by medical record documentation. RADV audits confirm the presence of the diagnoses related to the enrollee's HCC profile through the review of medical records submitted by the MA organizations for the purpose of a RADV audit; specifically, medical records from hospital inpatient facilities, hospital outpatient facilities, and physicians/practitioners (excluding suppliers of durable medical equipment, prosthetics, orthotics, and supplies). Risk adjustment discrepancies are identified when an enrollee's HCCs used for payment, which are based on MA organization self-reported data, differ from the HCCs assigned based on the medical record review performed by CMS through the RADV audit process. Risk adjustment discrepancies for sampled enrollees can then be aggregated to determine an average change in risk score as a result of RADV for sampled contract enrollees. The average change in risk score can be used to calculate an estimated total payment error amount for the larger universe of enrollees within an MA organization contract from which the sample is drawn, within specified confidence intervals using statistical extrapolation.

[120] Please refer to the May 23, 2014, final rule, "Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs Final Rule" (79 FR 29843, 29926) for a more detailed discussion of the timing and execution of the RADV audit and appeals process.

c. History of the Contract-Specific RADV Audits

RADV audits have existed in various forms and approaches for over 20 years. RADV audits began for payment year (PY) 1999, when the payment amounts made to MA organizations on a risk-adjusted basis were small (10 percent). During the period from PY 1999 until PY 2003, our RADV activity had an educational focus and was primarily intended to provide information that could be used by MA organizations to improve the accuracy of the risk adjustment data submitted to CMS for payment. Payment adjustments (recoveries) were limited to enrollee-level adjustments for those enrollees sampled in the audits and were not extrapolated to the overall contract. As a result, for the few MA contracts we audited, payment recovery amounts were small.

Risk adjustment payments using the CMS-HCC risk adjustment model began for the first time in PY 2004.[121] Because of various risk adjustment payment methodology changes required in the BBA and the Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554), CMS provided a payment "phase-in" under the new risk adjustment methodologies from 2000 to 2007, when MA organizations' payments were ultimately 100 percent risk-adjusted using the CMS-HCC risk adjustment model methodology. To prepare for implementation of a risk adjustment model in PY 2004 that was based on multiple sites of care, in 2001 CMS required MA organizations to begin submitting data on enrollees' hospital outpatient and physician office encounters, which increased the administrative data burden on MA organizations. Because of this burden and the associated phase-in of the new methodology, CMS considered PYs 2004 through 2006 as pilot years for the purpose of the RADV program and did not seek to recover improper payments for those payment years based on the audit results.

Improper payment recovery resumed for PY 2007, when we conducted two sets of RADV audits: (1) Pilot 2007, which involved 5 MA contracts; and (2) Targeted 2007, which

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[121] CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2004 Medicare+Choice (M+C) Payment Rates,* 4-5 (March 28, 2003), https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Advance2004.pdf.

involved 32 MA contracts. CMS began with the Pilot 2007 audit to test the methodology and make any changes needed before conducting the Targeted 2007 audit. CMS selected MA contracts after measuring the weighted average change in disease scores (risk scores) over the preceding 3-year period and grouping MA organization contracts as high, medium, or low relative to other MA contracts that were eligible for a RADV audit. Through these two sets of audits, we recouped $13.7 million. Payment adjustments were again limited to enrollee-level adjustments for those enrollees sampled in the audits and not extrapolated to the overall contract error rate. After CMS' findings were reported to each MA organization, any MA organization that disagreed with CMS' determinations could challenge them through an administrative dispute and appeals process that was established by regulation (75 FR 19678). This dispute and appeals process, as subsequently amended (75 FR 32858, 79 FR 29844, and 89 FR 30448), remains in effect and allows for the appeal of the medical record review determination and/or the payment error calculation through a three-level administrative review process, as outlined in § 422.311. To date, CMS has issued audit findings and initiated recovery activities for PYs 2011-2015.[122]

(1) Development of an Audit Methodology (PYs 2007 through 2010)

After the RADV audits were conducted for PY 2007, CMS paused RADV audits for PYs 2008, 2009, and 2010. CMS used those years to continue refining the methodology for the RADV audits, including the consideration of statistical methods to calculate extrapolated overpayments based on the errors identified in the audit sample. The use of extrapolation would enable us to make contract-specific payment adjustments rather than simply adjusting payments for specific enrollees from an audit sample, as we had done previously.

On December 20, 2010, we published an informal proposal on the CMS website that outlined our intended RADV methodology for: (1) selecting a statistically valid sample of enrollees from each audited MA contract; and (2) calculating a contract-specific payment

[122] https://www.cms.gov/data-research/monitoring-programs/medicare-advantage-risk-adjustment-data-validation-radv-program/radv-documents-data

adjustment by extrapolating the results of that sample. We invited public comment on this proposed methodology.

(2) Informal Proposal Comments and the FFS Adjuster

In response to the December 2010 informal proposal, some MA organizations suggested that CMS could not lawfully enforce the requirement of medical record documentation for diagnosis codes while making payments at the published rates. These MA organizations stated that there is a difference in auditing standards between Medicare FFS and MA diagnosis data because, in contrast to the MA organization-submitted diagnoses data, Medicare FFS data is "unaudited" by CMS. This difference purportedly exists because most FFS payments are made on the basis of the item or service provided and not the beneficiary's diagnosis or diagnoses. For example, an office visit is paid based on whether the evaluation and management service billed met Medicare coverage and payment rules, not based on what diagnoses are listed on the claim or in the medical record. As a result, they stated, the Medicare FFS data used to calculate MA organization payments will understate the cost of treating various conditions and, because erroneous diagnoses in the FFS claims data are used to calibrate the MA payment model, CMS must either adjust payment rates (by raising them) or adjust documentation standards (by loosening them) to resolve the alleged incompatibility between the payment rates and documentation standards. This proposed adjustment to the MA organization payment rates and/or documentation standard was referred to as an "FFS Adjuster."

These MA organizations ground their arguments in section 1853(a)(1)(C)(i) of the Act, which requires the Secretary to adjust payments to MA organizations for demographic and health related risk factors so as to ensure "actuarial equivalence." As described previously, the Act requires that we calculate risk-adjusted payments to MA organizations to ensure that MA organizations are paid appropriately based on the enrollees' health status and demographic characteristics. The current risk adjustment model does this by calculating plan enrollees' risk

scores and, in turn, using them to adjust the MA organizations' base payment rates, which are the rates for the average beneficiary.

As noted previously, CMS uses diagnostic information submitted by MA organizations to calculate risk scores using the CMS-HCC risk adjustment model, which is published in the Announcement of Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies each time it is updated (*see* section 1853(b) of the Act).[123] Risk scores are used to adjust payments to MA organizations. MA organizations may only report a diagnosis when that diagnosis is properly supported by the beneficiary's medical records. Medical records properly support a reported diagnosis when they comply with all CMS data and documentation requirements, which are described in current agency policy documents, including the Medicare Managed Care Manual.[124] In their annual contracts with CMS, MA organizations agree to operate in accordance with applicable Federal statutes, regulations, and policies, including policies described in the Medicare Managed Care Manual. MA organizations are also required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS (*see* § 422.310(e)).

(3) The 2012 Notice of Payment Error Calculation Methodology

The feedback received from industry in response to the informal proposal in 2010 was considered by CMS, and on February 24, 2012, we issued on our website[125] what we described as a final methodology for RADV contract-specific payment error calculation, to begin with PY 2011 RADV audits (referred to herein as the "2012 methodology"). That methodology described sampling techniques and a statistical calculation to extrapolate from the sample selected, as well as the use of an FFS Adjuster.[126] The 2012 methodology included the following components:

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[123] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.

[124] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019326.

[125] CMS *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits* at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf.

[126] *Id.* at 4-5.

- *Sampling Technique:* Under the 2012 methodology, up to 201 enrollees from each audited MA contract would be selected according to certain criteria. These criteria included, but were not limited to, the enrollees': (1) continuous enrollment in the MA contract for the entire data collection year and January of the payment year; (2) lack of end-stage renal disease (ESRD) or hospice status for the entire data collection year and January of the payment year; (3) enrollment in Medicare Part B coverage for the entire data collection year; and (4) assignment of at least one CMS-HCC based on diagnoses submitted by the MA organization for risk-adjustment payment. The RADV-eligible enrollees would then be ranked by risk score and divided into three equal strata (low risk score, average risk score, and high-risk score), with an equal number of enrollees randomly selected from each stratum (for example, 67 enrollees per stratum in the case of an audit of 201 enrollees).

- *Payment Error Calculation:* After medical records were reviewed, payment errors would be calculated for each selected enrollee based on the number of months the person was enrolled in the selected MA contract (and was not in ESRD or hospice status) during the payment year. A payment error amount for each stratum would be calculated, which could include both RADV-identified overpayments and underpayments, and an overall payment error estimate for the audited contract would be derived, along with a 99 percent confidence interval around the payment error estimate.

- *FFS Adjuster:* As part of the 2012 methodology, we also stated that we would apply a FFS Adjuster before finalizing the overpayment amount. The 2012 methodology stated that the actual value of the FFS Adjuster would be calculated by CMS based on a RADV-like review of medical records submitted to support FFS claims data. CMS never calculated or implemented an FFS adjuster for any RADV audits.

(4) The 2018 RADV Proposed Rule

In the 2018 proposed rule (83 FR 54982), to enhance transparency and provide ample notice to MA organizations, we proposed to codify in regulation our methodological approach to

RADV audits that would apply to all the payment year audits that had not yet been finalized. These methodologies would apply to PY 2011 and subsequent years and included our prior proposal to use extrapolation and a new proposal not to apply an FFS Adjuster to calculate RADV audit overpayments.

(5) The 2023 RADV Final Rule

In the February 1, 2023, **Federal Register** (88 FR 6643), we published a final rule. This final rule codified in regulation that, as part of the RADV audit methodology, CMS would extrapolate RADV audit findings beginning with PY 2018 and would not extrapolate RADV audit findings for PYs 2011 through 2017. We also finalized a policy whereby CMS would not apply an FFS Adjuster in RADV audits. We also finalized the requirement that MA organizations remit improper payments in a manner specified by CMS. CMS subsequently issued final, non-extrapolated RADV audit results for PYs 2011-2015 and published audit methodologies for PYs 2018-2021, and PY 2024.

On September 25, 2025, the U.S. District Court for the Northern District of Texas vacated this final rule, and CMS is currently appealing that decision.[127]

2. Discussion of Proposals

a. Extrapolation of RADV Audit Findings

(1) Use of Extrapolation in the Medicare Program

Extrapolation, or the act of estimating a value (such as an overpayment amount for a Medicare provider) based on a statistically valid sample of units (such as Medicare claims), has historically been a standard part of auditing practice at CMS. There is significant guidance, including case law and best practices from HHS and other Federal agencies, stating that extrapolation may be utilized as a valid part of calculating improper payments. Courts have held that sampling and extrapolation is a valid method of calculating improper Medicare payments, so

127 *Humana Inc. v. Becerra,* 801 F.Supp.3d 624 (N.D. Tex. 2025), *appeal docketed sub nom. Humana Inc. v. Kennedy*, No. 25-11082 (5th Cir. Nov. 21, 2025).

long as statistically valid methods are used. *See United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1, 18 n.19 (1st Cir. 2005) (noting that "sampling of similar claims and extrapolation from the sample is a recognized method of proof" for the United States in an affirmative case seeking recovery under a common-law theory); *see also Ratanasen v. California Dep't of Health Servs.*, 11 F.3d 1467, 1469-71 (9th Cir. 1993) (collecting cases in which sampling and extrapolation have been approved in the Medicaid context, and "join[ing] other circuits in approving the use of sampling and extrapolation as part of audits in connection with Medicare and other similar programs"); *Chaves Cnty. Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 917–23 (D.C. Cir. 1991). The authority to use sampling and extrapolation in Medicare audits is grounded in our statutory and regulatory authority to audit providers and recoup improper payments. *See Chaves*, 931 F.2d at 919 (interpreting the Medicare statute to allow for a "sample adjudication procedure" followed by extrapolation from that sample, which "is reasonable given the logistical imperatives recognized by courts in other comparable circumstances").

Sampling and extrapolation have been used to calculate improper payments in Medicare FFS (Part A and Part B) for decades. CMS formally approved of this technique in 1986 (HCFA Ruling 86-1), but Medicare Administrative Contractors (MACs), which are responsible for determining medical necessity and paying Medicare FFS claims, have been using it "at least since 1972." *Chaves*, 931 F.2d at 921; *see also id.* at 913 (explaining that "sample adjudication has been used in previous instances involving post-payment review of 'coverage determinations' under Part A," and that HCFA Ruling 86-1 "simply reiterated [the agency's] belief that it had the latitude to employ sample audits on post-payment review to efficiently recoup overpayments for non-covered services"). Medicare contractors currently use established sampling and extrapolation techniques when determining overpayments in accordance with Chapter 8 of the Medicare Program Integrity Manual. In 1991, the United States Court of Appeals for the District of Columbia Circuit, in *Chaves*, upheld the use of this audit methodology against arguments that the Medicare statute required individualized review of claims submitted by providers. *Id.* at 922.

The MMA imposed limits on the use of sampling and extrapolation in Medicare payment decisions in the context of Part A and Part B. Since 2003, Medicare Part A and Part B extrapolation under section 1893(f)(3) of the Act has been limited to instances in which the Secretary determines either that "there is a sustained or high level of payment error" or that "documented educational intervention has failed to correct the payment error." No similar limitation applies to the MA program, and CMS announced its intention to use extrapolation in RADV audits in the 2012 notice.

As previously discussed, sampling and extrapolation is a generally accepted audit technique in the Medicare context, and the Act does not apply any limits to the use of extrapolation in the MA program. Therefore, we believe that CMS has the authority to implement this audit methodology in RADV audits for any case in which a RADV audit identifies unsupported medical diagnoses resulting in improper risk-adjusted payments. We further believe that extrapolation is a reasonable approach to our RADV audits, given the sustained and high level of risk adjustment payment errors, as previously described, and volume of diagnosis data submitted by MA organizations.

(2) Extrapolation Proposal

CMS proposes extrapolating contract-specific RADV audit findings using statistically valid random sampling techniques. Given the volume of diagnosis data submitted by MA organizations, amount of improper payments identified under the MA program, interest in determining an accurate recovery amount for each audited MA plan, and importance of protecting the overall integrity of the program, we believe that it is in the public interest for CMS to apply extrapolation to PY 2018 and all subsequent years. Implementation of extrapolation and the other audit methodologies in this proposed rule will allow CMS to act in compliance with the improper payment obligations under the Act (most recently updated as part of the Payment Integrity Information Act of 2019 (PIIA), Pub. L. No. 116-117, 134 Stat. 113 (2020)), as well as our fiduciary responsibility to recover funds due to the Medicare Trust Funds.

CMS proposes to employ statistical methods to determine statistically valid sample sizes, accurately identify payment error, and extrapolate to the universe of enrollees from which the sample is selected. These statistically valid methods may include applying one or more RADV audit methodologies for any given RADV audit. In addition, while CMS views extrapolation as a statistically valid methodology for RADV audits, the agency may, at times, use its discretion to not utilize extrapolation in a particular instance. For example, there may be unforeseen circumstances in which the statistical validity of the sample is disturbed (such as the need to exclude a large number of cases from the sample due to the loss of medical records in a natural disaster) and extrapolation is no longer possible, despite the initial intent to do so. There may be other limited instances in which CMS seeks to collect overpayments associated only with enrollees in a given sample or wishes to perform only a probe sample of RADV reviews without the use of a statistically valid sample and yet will seek to recover any identified, non-extrapolated overpayments. The OIG may also independently decide not to extrapolate for reasons outside the control of CMS, and CMS will still recover those overpayments in accordance with requirements. To account for this, we are proposing § 422.311(a)(2) to read, "CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years." However, CMS intends for extrapolation to be the standard practice for RADV audits beginning with PY 2018.

Any sampling and extrapolation methodologies adopted by CMS for RADV audits will be focused on MA organization contracts and enrollees' HCCs that, through statistical modeling and/or data analytics, are identified as being at highest risk for improper payments. This is an appropriate approach to any Federal MA audit that seeks to recoup taxpayer dollars that have been inappropriately paid to MA organizations for diagnoses that are not supported in the medical record. This approach was also recommended by the GAO in a 2016 report titled "Fundamental Improvements Needed in CMS' Effort to Recover Substantial Amounts of

Improper Payments."[128] The GAO recommended that CMS "modify [its] selection of contracts for contract-level RADV audits to focus on those contracts most likely to have high rates of improper payments by taking actions such as the following: selecting more contracts with the highest coding intensity scores; excluding contracts with low coding intensity scores; selecting contracts with high rates of unsupported diagnoses in prior contract-level RADV audits; if a contract with a high rate of unsupported diagnoses is no longer in operation, selecting a contract under the same MA organization that includes the service area of the prior contract; and selecting some contracts with high enrollment that also have either high rates of unsupported diagnoses in prior contract-specific RADV audits or high coding intensity scores."[129]

CMS is not required to set forth all potential sampling methodologies for calculating an extrapolated payment error through regulatory provisions. However, in the interest of transparency, we are choosing to inform MA organizations about our plans to use various sampling and extrapolation methodologies in RADV audits, as CMS deems appropriate, through rulemaking.

In the 2018 proposed rule, we stated that, given the amount of improper payments identified under the MA program, interest in determining an accurate recovery amount for each audited MA plan, and importance of protecting the overall integrity of the program, we believed that it was in the public interest for CMS to apply the RADV payment error methodology or methodologies adopted through this rulemaking to PY 2011 and all subsequent years. In the 2023 final rule, we announced that extrapolation would instead begin with the PY 2018 RADV audits rather than PY 2011, as proposed. This change was made due to our fiduciary duty to protect taxpayer dollars from overpayments, certain operational considerations, and public comments on the timeliness of RADV audits.

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[128] GAO, at 26, https://www.gao.gov/assets/gao-16-76.pdf (April 2016).
[129] *Id.*

We also note that our publication of audit methodologies for PYs 2018-2021 put MA organizations on further notice that CMS plans to calculate a contract-specific payment error for PY 2018 and subsequent payments year by extrapolating from its review of a statistically valid sample of enrollees, and that MA organizations have never been entitled to receive or retain payments associated with HCCs that cannot be validated by medical records.

In addition to codifying our existing authority to use contract-specific extrapolation techniques in the RADV context, we also propose to use potential methodologies for sampling and extrapolation that are based on a particular sub-cohort or sub-cohorts in a given payment year. For example, a sub-cohort could be the enrollees for whom a particular HCC or one of a related set of HCCs (such as HCCs for diabetes conditions) was reported. After choosing an MA contract and a sub-cohort or sub-cohorts to audit, we would select a statistically significant sample of enrollees in the sub-cohort or sub-cohorts. After reviewing these enrollees' medical records that are submitted by the MA organization, we would use statistical extrapolation to calculate and recoup the improper payments made to the audited MA contract for all enrollees in the sub-cohort or sub-cohorts in that payment year.

Using a sub-cohort methodology, such as one focused on enrollees with high-risk HCCs, would allow us to use a smaller sample size to calculate a statistically valid extrapolated improper payment amount. This is possible because, when selecting a sample from a smaller population (that is, a sub-cohort of enrollees), one can still achieve an acceptable level of statistical confidence with that smaller sample size. This sub-cohort-based audit methodology would also allow us to spread our audit resources across a wider range of MA contracts and focus on cohorts of enrollees that raise programmatic concerns, while also reducing operational burden on both CMS and the MA organizations due to the reduced sample size needed to calculate improper payments.

We emphasize that neither proposed methodology is meant to displace our longstanding authority to audit the medical records of specific enrollees who we believe may be associated

with improper payments or to use any statistically valid audit methodology on a case-to-case basis. If we finalize one or more sampling and extrapolation methodologies through this rulemaking, we will announce any future changes to that methodology (or those methodologies) through the Health Plan Management System (HPMS) or other appropriate means.

We also propose that MA organizations would be required to remit extrapolated recovery amounts from RADV audit findings in a manner specified by CMS, typically through CMS' payment system, the Medicare Advantage and Prescription Drug system (MARx), as offsets to MA plans' monthly capitation payments. In the event that the recovery amount exceeds the payment in one month, we propose that the recovery be spread across adjustments for multiple months until the full amount plus applicable interest is recouped. In some situations, payment by wire transfer may be necessary. We also propose that CMS might likewise require MA organizations to remit such recovery amounts based upon audit findings by the HHS-OIG.

We also propose to reissue our RADV dispute and appeals regulations in § 422.311, to conform with the proposed audit methodology provisions. Specifically, consistent with our other proposed policies, we propose to reissue § 422.311 by including language to clarify that recovery of improper payments from MA organizations will be conducted according to the Secretary's payment error calculation methodologies and recovery procedures, and that CMS will apply extrapolation to RADV audits beginning with PY 2018.

b. Fee-For-Service Adjuster Concept

(1) Description of an FFS Adjuster

As previously described, risk adjustment ensures that MA organizations are paid appropriately for their plan enrollees, and section 1853(a)(1)(C) of the Act requires that we calculate risk-adjusted payments to MA organizations based on specific criteria, such as age, disability status, sex, institutional status, and health status. As discussed earlier, MA organizations' payments are calculated using the CMS-HCC risk adjustment model, which is

published each time it is updated (see section 1853(b) of the Act).[130] Additionally, an MA organization may only report a diagnosis, and claim the associated payment, when that diagnosis is properly supported by the beneficiary's medical records. Medical records properly support a reported diagnosis when they comply with all CMS data and documentation requirements, which are described in current agency regulations and policy documents, including Chapter 7 of the Medicare Managed Care Manual and those on the Customer Service and Support Center website.[131] Plans are also required to submit a sample of medical records for the validation of this risk adjustment data (*see* § 422.310(e)).

Some MA organizations have suggested that CMS cannot lawfully enforce the requirement of medical record documentation for diagnosis codes while making payments at published rates. These MA organizations state that there is a difference in auditing standards between Medicare FFS and MA diagnosis data. In contrast to the MA organization-submitted diagnosis data, these MA organizations claim that Medicare FFS data is "unaudited" by CMS and presumably contains erroneous diagnosis codes not properly supported by beneficiaries' medical records. As a result, they state, the Medicare FFS data used to calculate MA organization payments will understate the cost of treating various conditions. MA organizations state that CMS must raise payment rates to MA organizations or relax the documentation standard that CMS applies to reported medical diagnoses to address what they refer to as the presence of erroneous diagnoses in the FFS claims used to calibrate the CMS-HCC model. MA organizations refer to this concept of a proposed adjustment to the payment rates and/or documentation standard for MA organizations as an "FFS Adjuster." These MA organizations ground their arguments in section 1853(a)(1)(C)(i) of the Act, which requires the Secretary to adjust payments to MA organizations for demographic and health related risk factors to ensure

[130] https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.
[131] See the following link to access CMS manuals: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c07.pdf. See the following link for the MA Customer Service and Support website: https://csscoperations.com/.

"actuarial equivalence." According to these MA organizations, an FFS Adjuster would either adjust payment rates (by raising them) or adjust documentation standards (by loosening them) to resolve the alleged incompatibility between the current rates and current documentation standards. In the 2012 methodology, using the term somewhat differently, CMS said that it would "apply a Fee-for-Service Adjuster (FFS Adjuster) amount as an offset to the preliminary recovery amount" calculated for RADV audits under that methodology.

(2) FFS Adjuster Proposal

We are proposing to not apply an FFS Adjuster to RADV audits. The "actuarial equivalence" and "same methodology" provisions in the statute do not apply to the obligation of an MA organization to report and return improper payments for diagnoses lacking medical record support, including those improper payments identified during a RADV audit, as discussed in detail later. We also believe that it would not be reasonable to interpret the Act as requiring a reduction in payments to MA organizations by at least a statutorily set minimum percentage pursuant to the coding pattern adjustment, while at the same time prohibiting CMS from enforcing longstanding documentation requirements by requiring an offset to the recovery amounts calculated for CMS audits, as discussed in detail as follows.

(3) Actuarial Equivalence

Some MA organizations have contended that an FFS Adjuster is required in RADV audits to ensure "actuarial equivalence" between payments to MA plans and payments under the Medicare FFS program. Some have also contended that the "same methodology" provision of section 1853(b)(4)(D) of the Act requires the application of an FFS Adjuster in RADV audits.

We believe that the "actuarial equivalence" requirement under section 1853(a)(1)(C) of the Act and "same methodology" provision under section 1853(b)(4)(D) of the Act do not require the use of an FFS Adjuster in RADV audits. As described by the D.C. Circuit, these provisions do not apply to the obligation to return improper payments for MA organization diagnosis codes that are unsupported by medical records. *See UnitedHealthcare Ins. Co.* v.

Becerra, 16 F.4th 867, 869, 891-92 (D.C. Cir. 2021), *cert. denied,* 142 S. Ct. 2851 (U.S. June 21, 2022). Although the D.C. Circuit did not address the RADV audit context in its decision in *UnitedHealthcare*, our position is consistent with the D.C. Circuit's reasoning in that case. *Id.*

In *UnitedHealthcare*, a group of MA organizations challenged the Secretary's Part C Overpayment Rule (the "Overpayment Rule") (79 FR 29844), which implemented section 6402 of the Affordable Care Act (Pub. L. 111-148) and required MA organizations to self-report and return payments associated with MA organization diagnosis codes not supported by medical record documentation. The district court invalidated the Overpayment Rule. *See UnitedHealthcare Ins. Co. v. Azar*, 330 F. Supp. 3d 173, 192 (D.D.C. 2018).

However, the D.C. Circuit reversed the district court, holding that the actuarial equivalence provision applies only to how CMS risk adjusts the payments it makes to MA organizations, and not to the obligation of MA organizations to return improper payments for diagnosis codes, submitted by MA organizations to CMS, lacking medical record support. *See UnitedHealthcare*, 16 F.4th at 883-887. The D.C. Circuit also held that even if the actuarial equivalence provision applied, plaintiffs' claims would still fail because they did not meet their burden in showing, either through empirical evidence or persuasive logic, that application of the Overpayment Rule would lead to systematic underpayment of MA organizations. *Id.* at 887 through 891.

While the D.C. Circuit decision pertained only to the Overpayment Rule and declined to address RADV audits, its reasoning applies just as strongly in the RADV context and supports our proposed conclusion that an FFS Adjuster is neither required nor appropriate to reduce a RADV audit overpayment. "The role of the actuarial-equivalence provision is to require CMS to model a demographically and medically analogous beneficiary population in Original Medicare to determine the prospective lump-sum payments to [MA organizations]." *Id.* at 870. The RADV audit program, like the Overpayment Rule, arises post-payment to require MA organizations to refund any payment to which they are not entitled, based on diagnoses that lack

support in the medical record. The purpose of RADV audits is to recover payments that were made improperly based on diagnoses not supported by medical record documentation. If a payment is made to an MA organization based on a diagnosis code not supported by medical record documentation, the entire payment for that code is in error and should be recovered in full because the payment standard has not been met.

We also believe it would be unreasonable to interpret the Act as requiring a minimum reduction in payments in one provision (the coding pattern provision), while at the same time prohibiting CMS in an adjacent provision (the actuarial equivalence provision) from enforcing those longstanding documentation requirements (by requiring a reduction to the recovery amount calculated for CMS audits). To the contrary, because the Act requires CMS to reduce payments to MA organizations by at least a specific minimum percentage, the only reasonable interpretation of the Act is that CMS would pay MA organizations at those reduced rates, under the existing payment model,[132] and enforce the longstanding documentation requirements.

Our proposal is consistent with the conclusion of the D.C. Circuit, which is that the actuarial-equivalence requirement is not an "entitle[ment] . . . to a precise payment amount" for a Medicare Advantage insurer, but only "an instruction to the Secretary regarding the design of the risk adjustment model as a whole . . . describ[ing] the type of 'payment amount[s]' that the risk adjustment model should produce"; "[i]t does not directly govern how CMS evaluates the validity of diagnoses or defines 'overpayment.'" *UnitedHealthcare*, 16 F.4th at 885-86.

(4) Coding Pattern Adjustment

Section 1853(a)(1)(C)(ii) of the Act requires the implementation of a minimum coding pattern adjustment to reduce risk scores of MA beneficiaries, and therefore MA payment rates, until the Secretary implements risk adjustment using Medicare Advantage diagnostic, cost, and use data. This minimum coding pattern adjustment accounts for differences in coding patterns between MA and Medicare FFS, given that MA organizations have a greater incentive than FFS

[132] Any changes to the CMS-HCC payment model are published in the annual payment notice.

providers to report diagnoses. To meet this requirement, each year, CMS has implemented an adjustment to offset the effects on MA risk scores of higher levels of coding patterns in MA relative to FFS. (See section 1853(a)(1)(C)(ii) of the Act.) Under section 1853(a)(1)(C)(ii)(III) of the Act, the minimum adjustment factor for 2019 and each subsequent year is 5.90 percent. CMS has, each year, implemented the minimum coding pattern adjustment reduction required by statute.

Some MA organizations have expressed concern that using extrapolation without applying an FFS Adjuster to payment recoveries achieved through RADV audits will overlap with coding pattern adjustments or create a double recovery by CMS. As CMS has explained in its annual MA Advance Notices and Rate Announcements, the coding pattern adjustment, unlike RADV, is not intended to address unsupported or inaccurate codes reported by MA organizations in particular instances but only the general practice, relative to Medicare FFS, of identifying more diagnosis codes, including codes that are nonetheless accurate.[133] The coding pattern adjustment provision of the statute supports our proposal not to apply an FFS Adjuster. We briefly review the history of that provision.

The coding pattern adjustment was enacted as part of the Deficit Reduction Act of 2005. (Pub. L. 109-171 (February 8, 2006), codified at 42 U.S.C. 1395w-23(a)(1)(C)(ii)(I) and (II).) The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), section 1853(a)(1)(C)(ii) of the Act was amended to require that the adjustment be at least 4.71 percent in 2014, rising annually to at least 5.7 percent in 2019. (Pub. L. 111-152, tit. I, subtit. B, section 1102(e), 124 Stat. 1046.) (For payment years 2010 to 2013, CMS applied a 3.41 percent adjustment.[134]) Section 1853(a)(1)(C)(ii)(III) of the Act was subsequently amended again in the

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[133] Announcement of Calendar Year (CY) 2011 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter at 19 (April 5, 2010); *see also* Announcement of Calendar Year (CY) 2017 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter at 54 (April 4, 2016); Announcement of Calendar Year (CY) 2012 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter at 37-38 (April 4, 2011).

[134] Announcement of Calendar Year (CY) 2010 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies at 19-29 (April 6, 2009).

American Taxpayer Relief Act of 2012 to require the Secretary to make a reduction of at least 4.91 percent in 2014, rising to at least 5.9 percent by 2019. (Pub. L. 112-240, tit. VI, subtit. C, section 639, 126 Stat. 2357.) As noted previously, it would be unreasonable to interpret the Act as requiring a minimum reduction in payments in one provision (the coding pattern provision), while at the same time prohibiting CMS in an adjacent provision (the actuarial equivalence provision) from enforcing those longstanding documentation requirements (by requiring an offset to the recovery amount calculated for CMS audits). Section 1853(a)(1)(C)(ii) of the Act requires a minimum coding pattern adjustment to reduce the risk scores of all MA beneficiaries, and therefore, MA payment rates. Such a minimum coding pattern adjustment accounts for differences in coding patterns between MA and Medicare FFS, given that MA organizations have a greater incentive than FFS providers to report diagnoses.

(5) Documentation Requirements

Some MA organizations have stated in prior rulemaking comments that not using an FFS adjuster imposes new documentation standards on them, but CMS audits reinforce longstanding documentation requirements. The purpose of RADV audits is to recover improper payments resulting from diagnoses that are not supported in the medical record documentation, which is a longstanding documentation standard that applies to all plans equally and regardless of whether the plan is subject to a RADV audit. The objective of an audit is to promote fair and impartial recovery of improper payments due to insufficient documentation in accordance with regulations. This proposal would not impose a new documentation standard on MA organizations, nor is there a distinction in the documentation standards between the MA and FFS Medicare programs. Under section 1857(d)(2), each MA contract provides the Secretary with the right to audit and inspect any books and records of the MA organization that pertain to services performed or determinations of amounts payable under the contract. Similarly, Section 1815(a) of the Act (Medicare Part A) states that "no such payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to

determine the amounts due such provider under this part for the period with respect to which the amounts are being paid or any prior period." Additionally, section 1833(e) of the Act (Medicare Part B) states that "[n]o payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period." Section 1172 of the Health Insurance Portability and Accountability Act (HIPAA) (Pub. L. 104-191) requires both providers and health plans to use standard content, formats, and coding for health care transactions. Accordingly, all parts of Medicare generally require program participants to submit documentation necessary to support Medicare payments.

As we noted in our April 15, 2022, Health Plan Management System (HPMS) memorandum, *Reminder of Existing Obligation to Submit Accurate Risk Adjustment Data*, MA organizations must submit data that conforms to all relevant national standards, including the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Guidelines for Coding and Reporting requirement that diagnoses be documented in patients' medical records. (*See* §§ 422.310(d)(1); 45 CFR 162.1002(c)(2), (3).) The diagnosis codes and other risk adjustment information that MA organizations submit directly affect the calculation of CMS payments to the MA organization. A diagnosis code that is not documented in a patient's medical record is not a valid basis for CMS risk adjustment payments to an MA organization. *UnitedHealthcare*, 16 F.4th at 869, 877.

In addition, the Secretary has adopted various organizations' formats and code sets, including the ICD-10 and the ICD Guidelines, which is the national standard for both FFS and MA. See 45 CFR 162.1002. CMS has always required proper medical record documentation in order for any reported diagnosis code or claim to be valid. (*See, for example*, *UnitedHealthcare*, 16 F. 4th at 869 ("[n]either Congress nor CMS has ever treated an unsupported diagnosis for a beneficiary as valid grounds for payment to a Medicare Advantage insurer"). That is the

consistent policy throughout the Medicare program, including MA and FFS.[135] (See § 422.310 ("MA organizations must submit data that conform to CMS' requirements for data equivalent to Medicare fee-for-service data, when appropriate, and to all relevant national standards.") Thus, we do not believe that RADV audits impose any new level of burden on providers or violate any initiatives to reduce that burden.

As such, we propose to not apply an FFS Adjuster to RADV audit overpayments.

c. Improving the Hardship Exceptions Process

MA record retention requirements incorporated in MA contracts have been in place since the beginning of the MA program. Under § 422.504(d), MA organizations are required to maintain records and other documentation for 10 years to accommodate the periodic auditing of financial records for such purposes as determining Medicare utilization, costs, and amounts payable under the contract. Further, § 422.504(i) extends these record retention requirements to providers of health care services under contract with the MA organization. This regulation further specifies that the Federal Government has the right to audit an MA organization through 10 years from the end of the final contract period.

However, CMS understands that there may be extraordinary circumstances beyond MA organizations' control that may make it difficult to meet medical record submission or other audit requirements. CMS historically implemented a hardship exception process through sub-regulatory guidance for prior payment year audits. We are now proposing to codify this process in regulation by adding a new subparagraph § 422.310(e)(1) to allow MA organizations to request a hardship exception, as prescribed by CMS, if they cannot submit medical records timely as required.

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[135] FFS Medicare claims are subject to error correction and payment adjustment when they are based on diagnosis codes not supported by the medical record. *See* Medicare Program Integrity Manual Ch. 3 & Ch. 6, §§ 3.3.1.1, 3.3.2.1, 3.6.2.4, 6.5.2, 6.5.3., https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019033.

First, we propose that MA organizations may submit a hardship exception request for: (1) the entire MA contract; (2) a sampled enrollee and all the related audited HCCs; or (3) specific audited HCCs. An MA organization may submit multiple hardship exception requests, if necessary, but all supporting documentation must be submitted before the hardship exception request submission deadline. Deadlines to request a hardship exception would be specified in sub-regulatory guidance issued prior to the start of a payment year audit. An MA organization would be required to withdraw a specific hardship exception request before resubmitting it with modifications. For example, if an MA organization submitted a hardship exception request for one or more audited HCCs for a specific enrollee, the MA organization would be required to withdraw that existing hardship exception request submission prior to adding another HCC to the hardship exception request and resubmitting the request to CMS. If an MA organization submits a valid medical record (MR) for an audited HCC(s) for which it has submitted a hardship exception request, then the hardship exception request and any decision made by CMS (for the related audited HCC(s)) for the request would be rendered moot. In other words, the valid MR submission would supersede any hardship exception request.

Second, we propose that an MA organization would be required to submit supporting documentation with a hardship exception request that clearly demonstrates an extraordinary circumstance(s) exists and includes all relevant details required for CMS to comprehensively assess the incident or issue. Supporting documentation includes, but is not limited to, any communications associated with the incident and all available evidence substantiating that the incident occurred. MA organizations still have an obligation to pursue all potential medical record sources before submitting a hardship exception request and should review relevant record retention requirements. MA organizations should actively pursue and submit an alternative medical record that supports an audited HCC(s) when the initial medical record sought is unavailable or insufficient to support the audited HCC(s).

If an MA organization is unable to obtain the relevant medical record(s) and submits a hardship exception request for a sampled enrollee's, or group of sampled enrollees', audited CMS-HCCs, we propose that the MA organization would be required to submit documentation (such as verification of a United States Postal Service certified mail delivery or that a delivery attempt was made, or similar verifiable evidence) that it sought medical record documentation from all providers associated with diagnosis data that the MA organization submitted to CMS for the purpose of receiving risk adjusted payments for the sampled enrollee(s). Additionally, MA organizations should be aware of State requirements for medical records to be placed in the care of a custodian for a period of time when a health care provider's office closes. When a health care provider has closed, retired, passed away, changed ownership, or otherwise undergone a change that, according to State law, should have required their medical records to be placed in the care of a custodian, MA organizations should contact the custodian to request the relevant medical records. We propose that CMS would deny a hardship request if the MA organization failed to submit sufficient supporting documentation, including documentation of the MA organization's pursuit of all possible medical record sources. We also propose that hardship exception requests decisions would be final and not subject to appeal.

The following are examples of extraordinary circumstances that may meet CMS' definition of an extraordinary circumstance that may impede an audited MA organization's timely acquisition of medical records and the types of supporting documentation that CMS would expect to be submitted by the MA organization to substantiate the circumstances:

- *Natural Disaster or Declared Emergency*: Events such as hurricanes, wildfires, floods, or other declared emergencies that disrupt provider operations or access to records. Supporting documentation includes FEMA or State emergency declarations, provider attestations, news releases, and facility closure notices associated with the natural disaster or declared emergency.

- *Public Health Emergency*: Public health events that significantly impact staffing, operations, or access to medical records. Supporting documentation includes government-issued emergency declarations, internal contingency plans, and provider attestations.

- *Legal or Regulatory Restrictions*: Court orders, subpoenas, or legal constraints preventing access to records within required timeframes. Supporting documentation includes court orders, legal correspondence, attestation from legal counsel, and any proof of seizure or unavailability including official documentation showing records were seized.

- *Major System or Technology Failure*: Significant IT outages or cybersecurity incidents. Supporting documentation includes incident reports, vendor outage notices, and other documentation such as system logs, error reports, security audit reports, data recovery attempts, incident documentation, and/or breach or loss of data reports.

- *Provider's Office Closed and Custodial Requirements Lapsed*: A provider retired, sold, or closed their practice preventing access to records within the required timeframe and the State law custodial requirements have lapsed. Supporting documentation includes an announcement, news report, or signed attestation indicating closure. Submissions regarding provider office closures would take into consideration State law custodian of record requirements, and evidence that the enrollee's record cannot be accessed by any other provider or practice.

- *Other Extraordinary Circumstances*: Circumstances beyond the organization's control that materially impact the retrieval of medical record documentation. Supporting documentation includes a detailed written explanation and third-party attestations or corroborating documentation.

These examples are not exhaustive and would not guarantee approval of a submitted hardship exception request. Furthermore, MA organizations failing to submit sufficient supporting documentation, including documentation of the MA organization's pursuit of all possible medical record sources, will result in CMS denying a hardship exception request.

CMS would not consider the following scenarios to be justification for granting a hardship exception:

- Reliance solely on State law record retention periods that are shorter than CMS' 10-year record retention requirement.
- Health care providers not responding to a request.
- Issues related to lost records.
- Provider office closures, or retired or deceased health care providers where State law custodial requirements have not lapsed.
- Medical practice transfers.
- Human resource issues.
- Ordinary IT issues (for example, system upgrade issues, routine data migration issues, incomplete vendor handovers) that result in missing or inaccessible records.

MA organizations are reminded of their obligation to pursue alternative medical records in these situations. We seek comments on the hardship exception request process and MA organizations' requirement to submit supporting documentation.

d. Retroactivity

We do not believe that the RADV audit policies proposed in this rule impose any new requirements on MA organizations that could be construed as retroactive. We may begin to conduct new RADV audits or finalize results from existing audits for multiple payment years before finalizing the policies in this rule, pursuant to our longstanding authority under § 422.310(e) to review the medical records of any MA enrollee and recoup improper payments identified.

As discussed in the Discussion of Proposals section, CMS has a long-established historical record of using extrapolation in the Medicare program. There is significant guidance, including case law and best practices from HHS and other Federal agencies, stating that extrapolation may be utilized as a valid part of calculating improper payments. CMS first

announced its intention to use extrapolation in RADV audits with the publication of an informal proposal in 2010 and reaffirmed this intention in the 2012 methodology.[136] This intention was again announced in the 2018 RADV proposed rule (83 FR 54982) and subsequently finalized in the 2023 RADV final rule (88 FR 6643). CMS has also announced its intention not to apply an FFS adjuster in RADV audits since the 2018 RADV proposed rule and this policy intention was finalized in the 2023 RADV final rule.

Even if our proposal was determined to be a retroactive application of policy, a position with which we do not agree, it is in the public interest for CMS to apply extrapolation to past payment years, and, therefore, is authorized under the Act. CMS has the authority, in accordance with section 1871(e)(1)(A) of the Act, to apply retroactive changes in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability to items and services furnished before the effective date of the change, if the Secretary determines that "such retroactive application is necessary to comply with statutory requirements or failure to apply the change would be contrary to the public interest." Since the early development of RADV, CMS has repeatedly notified MA organizations and the public of its intent to extrapolate RADV audits results and published a methodology in 2012. We believe that recovering extrapolated improper amounts is necessary to comply with statutory requirements and advances the public interest by protecting the overall integrity of the Medicare program. As mentioned earlier, in fiscal year (FY) 2025 (based on calendar year 2023 payments), we estimated that CMS made over $21 billion in Part C overpayments, a figure representing over 5 percent of total Part C payments.[137] Due to significant growth in the MA program and the large volume of diagnosis data submitted by MA organizations, we are unable to recover this significant amount of

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[136] CMS *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits* at https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf.

[137] HHS, FY 2025 HHS Agency Financial Report, pg. 154, https://www.hhs.gov/sites/default/files/fy-2025-hhs-agency-financial-report.pdf. CMS made over $23 billion in total Part C improper payments. The improper payment measurement for the MA program in FY 2025 included both overpayments ($21 billion) and underpayments ($2 billion).

overpayment without the use of extrapolation. We have a statutory mandate under the PIIA to reduce improper payments and a fiduciary responsibility to recover funds due and owed to the Medicare Trust Funds.

As previously discussed, CMS, HHS-OIG, and the GAO have identified a significant volume of improper payments in the MA program,[138] and RADV audits are the primary way CMS ensures payment accuracy to MA organizations. As further discussed in the Regulatory Impact Analysis section of this proposed rule, CMS estimates extrapolated improper payment recoveries of approximately $9 billion per audit year beginning with the PY 2018 audits. We also believe that extrapolation will foster an additional sentinel effect of RADV audits on the improper payment rate as MA organizations improve their processes to report only those diagnoses that meet CMS requirements to be documented in the medical record in accordance with ICD-CM coding guidelines.

The core component of a RADV audit is to ensure that all diagnoses are properly supported by medical records. We only seek to recover improper payments received by MA organizations for HCCs that are not substantiated by enrollees' medical records. MA organizations have never been entitled to receive or retain payments associated with HCCs that cannot be validated by medical records, and it is impossible for MA organizations to submit, and CMS to audit, every medical record. CMS has never calculated or applied an FFS adjuster to any RADV audit findings and allowing MA organizations to retain Medicare funds for unsubstantiated diagnoses on this basis runs contrary to the statute. Therefore, applying the rule under the public interest exception in section 1871(e)(1)(A) of the Act would not upset any settled or reasonable reliance interests. This all serves the public interest by reducing the improper allocation of taxpayer dollars that can otherwise be used for other purposes within the

[138] For example, the FY 2025 HHS Agency Financial Report, pg. 154, https://www.hhs.gov/sites/default/files/fy-2021-hhs-agency-financial-report.pdf states that Part C Improper Payment Measurement (IPM) estimated approximately $21.4 billion in overpayments for reporting year 2025. https://www.hhs.gov/sites/default/files/fy-2025-hhs-agency-financial-report.pdf.

Federal Government, including solvency of the Medicare Trust Funds. Thus, a retroactive application of the rule is in the public interest within the meaning of section 1871(e)(1)(A) of the Act.

If a court were to find that any provision of this rule is impermissibly retroactive, we believe that the rule should remain in effect for any payment year that has not yet occurred or for other provisions not found to be retroactive. For example, if our proposed use of extrapolation for payment years prior to the publication of a final rule is determined to be impermissibly retroactive, the final regulation would still allow collection of extrapolated recoveries for subsequent payment years depending on what payment year is determined to be the triggering date for retroactive application.

To the extent a court may ultimately enjoin one provision of this section as finalized, CMS proposes that the other provisions should remain in effect, ensuring the continuity of the regulations. We propose that any provision of the requirements of this rule that is held to be invalid or unenforceable by its terms or as applied to any person, entity, or circumstance would be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding is one of utter invalidity or unenforceability, in which event we propose that the provision would be severable from the other provisions of this rulemaking and would not affect the remainder thereof or the application of the provision to persons or entities not similarly situated or to dissimilar circumstances.

We propose that if any section, subsection, sentence, clause, phrase, word, provision, or application of this proposed rule as finalized shall be found to be invalid, illegal, unconstitutional, or unenforceable, that finding shall not affect or undermine the validity of any other section, subsection, sentence, clause, phrase, word, provision, or application which can be enforced without the use of the offending provision. We request comments from the public on severability, particularly which policies could be severable, if finalized, and how the other policies in a final rule would operate absent those particular provisions.

V. Provider Enrollment Proposals

A. Provider Enrollment Background

1. Introduction

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers into the Medicare program. The overarching purpose of the enrollment process is to help confirm that providers and suppliers (hereafter collectively "providers" unless otherwise noted) seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all applicable Federal and State requirements to do so. The process is, to an extent, a "gatekeeper" that prevents unqualified and potentially fraudulent individuals and entities from entering and inappropriately billing Medicare. It has proven invaluable in this regard and is a vital component of Medicare program integrity.

Under 42 CFR 424.510, a provider or supplier must complete, sign, and submit to its assigned Medicare contractor the appropriate Form CMS-855 (OMB Control No. 09380685) application in order to enroll in the Medicare program and obtain Medicare billing privileges.[139] The Form CMS-855, which can be submitted via paper or electronically through the Internet-based Provider Enrollment, Chain, and Ownership System (PECOS) process, captures information about the provider or supplier that is needed for CMS or its contractors to determine whether the provider or supplier meets all Medicare requirements. Data collected during the enrollment process include but are not limited to: (1) general identifying information (for example, legal business name, tax identification number (TIN), and National Provider Identifier (NPI)); (2) licensure data; (3) practice locations; and (4) information regarding the provider's or supplier's owning and managing individuals and organizations.

The application is used for a variety of provider enrollment transactions, including the following:

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[139] Medicare Diabetes Prevention Program (MDPP) suppliers complete the Form CMS-20134 (Medicare Enrollment Application; Medicare Diabetes Prevention Program (MDPP) Suppliers) in lieu of the Form CMS-855. Except as stated otherwise, all references in this proposed rule to the Form CMS-855 include the Form CMS20134.

- Initial enrollment – The provider or supplier is: (1) enrolling in Medicare for the first time; (2) enrolling in another Medicare contractor's jurisdiction; or (3) seeking to enroll in Medicare after having previously been enrolled.

- Change of ownership – The provider or supplier is reporting a change in its ownership.

- Revalidation – The provider or supplier is revalidating its Medicare enrollment information in accordance with § 424.515.

- Reactivation – The provider or supplier is seeking to reactivate its Medicare billing privileges after it was deactivated in accordance with § 424.540.

- Change of information – The provider or supplier is reporting a change in its existing enrollment information in accordance with § 424.516.

Our provider enrollment regulations are generally codified in 42 CFR part 424, subpart P (currently §§ 424.500 through 424.575 and hereafter occasionally referenced as subpart P). They address, among other things, requirements that providers must meet to obtain and maintain Medicare billing privileges. Since 2006, we have issued numerous final rules designed to strengthen and clarify the provider enrollment process, such as the following:

a. The 2006 Provider Enrollment Final Rule

We published in 2006 a final rule titled, "Medicare Program; Requirements for Providers and Suppliers to Establish and Maintain Medicare Enrollment," which appeared in the Federal Register on April 21, 2006 (71 FR 20754). The final rule set forth certain requirements in 42 CFR part 424, subpart P that providers and suppliers must meet to obtain and maintain Medicare billing privileges.

b. The 2011 Provider Enrollment Final Rule

We published a final rule with comment period in 2011 titled, "Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers

and Suppliers," which appeared in the Federal Register on February 2, 2011 (76 FR 5862). This final rule with comment period implemented various provisions of the Act, as added by the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111-148) and as amended by the Health Care and Education Reconciliation Act (Pub. L. 111-152). These provisions included, among other things:

- Requiring the submission of application fees by institutional providers and suppliers as part of the Medicare, Medicaid, and CHIP provider enrollment processes.
- Establishing Medicare, Medicaid, and CHIP provider risk-based enrollment screening categories and corresponding screening requirements.
- Authorizing temporary moratoria on the enrollment of new Medicare, Medicaid, and CHIP providers and suppliers of a particular type (or the establishment of new practice locations of a particular type) in a geographic area when necessary to combat fraud, waste, or abuse.

c. The 2019 Provider Enrollment Final Rule

We published in 2019 a final rule with comment period titled “Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process,” which appeared in the **Federal Register** on September 10, 2019 (84 FR 47794). This rule implemented section 1866(j)(5) of the Act (as added by the Affordable Care Act), which permitted the Secretary to deny the enrollment of a Medicare, Medicaid, and Children's Health Insurance Program (CHIP) provider or supplier if--

- The provider or supplier has or previously had an affiliation with a provider or supplier that: (1) has uncollected debt; (2) has been or is subject to a payment suspension under a Federal health care program; (3) has been or is excluded by the Office of Inspector General (OIG) from Medicare, Medicaid, or CHIP; or (4) has had its Medicare, Medicaid, or CHIP billing privileges denied or revoked; and
- The Secretary determines that this affiliation presents an undue risk of fraud, waste, or abuse to the Medicare program.

This rule also established additional grounds for denying or revoking a provider's or supplier's Medicare enrollment based, in general, on problematic or otherwise non-compliant conduct by the provider or supplier. These provisions were designed to strengthen the integrity of the Medicare program and to protect Medicare beneficiaries.

Besides these final rules, we have made other regulatory changes to 42 CFR part 424, subpart P – virtually on an annual basis since 2020 -- to address various payment safeguard issues that have arisen.

Despite these rulemaking efforts, and as later explained in detail, several provider enrollment vulnerabilities remain and certain regulatory clarifications are needed. Therefore, we are proposing a number of provider enrollment provisions that we believe would help resolve these issues. They focus largely on: (1) DMEPOS supplier enrollment, including DMEPOS surety bonds; (2) Medicare Advantage enrollment requirements; and (3) additional denial and revocation grounds. We also are proposing provisions regarding Medicaid provider enrollment, discussed in section V.G of this proposed rule.

2. Legal Authorities

Although additional legal authorities are addressed later in this section V., our principal authorities for this proposed rule are:

- Section 1866(j) of the Act, which furnishes specific authority regarding the enrollment process for providers and suppliers; and
- Sections 1102 and 1871 of the Act, which provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

3. Medicaid and CHIP Provider Enrollment

As stated, we are also proposing a number of provider enrollment provisions relating to Medicaid and CHIP. These are addressed in section V.G. of this proposed rule.

B. DMEPOS Supplier Provisions

Among the types of providers and suppliers that must enroll in Medicare to bill the

Medicare program are DMEPOS suppliers. Such suppliers include, but are not limited to, the following:

- Medical supply companies that exclusively furnish DME like wheelchairs, walkers, and canes.
- Physicians and practitioners who provide DMEPOS to their own patients.
- Home health agencies (HHAs) and hospitals that provide DMEPOS to their own patients.
- Oxygen and oxygen equipment suppliers.
- Prosthetists and orthotists.
- Pharmacies.

DMEPOS suppliers enroll in Medicare via the Form CMS-855S application (Medicare Enrollment Application - Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS); OMB Control No. 0938-1056). Per 42 CFR 424.57(b)(1) -- and excluding locations it utilizes solely as warehouses or repair facilities -- the supplier must separately enroll each physical location it uses to furnish Medicare-covered DMEPOS.

Suppliers of DMEPOS have long presented to the Medicare program an elevated risk of fraud, waste, and abuse – historically, perhaps the highest of all Medicare provider and supplier types. Numerous HHS-OIG reports since 1998 have noted serious program integrity problems with DMEPOS suppliers, and we recently outlined a significant number of DMEPOS supplier criminal and False Claims Act cases.[140] Recognizing this threat, CMS over the years has established particularly stringent requirements that DMEPOS suppliers must meet to enroll and

[140] See the proposed rule titled, "Medicare and Medicaid Programs; Calendar Year (CY) 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies" (90 FR 29108), published in the **Federal Register** on July 2, 2025. CMS on February 27, 2026, also imposed a nationwide temporary moratorium on the enrollment of DMEPOS medical supply companies due to fraud, waste, and abuse concerns. *See* "Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of Nationwide Temporary Moratoria on Enrollment of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Medical Supply Companies" (91 FR 9855), which appeared in the **Federal Register** on February 27, 2026.

maintain enrollment in Medicare. To illustrate, DMEPOS suppliers under 42 CFR 424.518(c) are one of only a few provider and supplier types subject to the highest and strictest level of screening during the enrollment process. (In fact, they were one of only two types originally assigned to this high-risk screening category in 2011 - the other being HHAs). This level of screening includes: (1) a site visit; and (2) submission of fingerprints of the supplier's 5 percent or greater owners for a Federal Bureau of Investigation (FBI) criminal background check. There are other regulatory provisions besides the basic provider enrollment requirements in 42 CFR part 424, subpart P (§§ 424.500 through 424.575) that DMEPOS suppliers must meet. These requirements include, but are not limited to, the following:

- Compliance with the DMEPOS supplier standards in § 424.57(c).
- Acquisition and maintenance of a surety bond consistent with § 424.57(d).
- Compliance with DMEPOS quality standards.
- Accreditation by a CMS-approved DMEPOS accrediting organization.

The foregoing underscores the serious and continued payment safeguard challenges associated with DMEPOS suppliers. We accordingly propose several regulatory revisions related to DMEPOS supplier enrollment.

1. Medicare Surety Bonds

a. Introduction

On January 2, 2009, we published in the **Federal Register** (74 FR 166) a final rule to implement section 1834(a)(16)(B) of the Act.[3] The rule established a new § 424.57(d) requiring DMEPOS suppliers that were not otherwise exempted to submit a surety bond in the amount of at least $50,000 to the National Supplier Clearinghouse (now the National Provider Enrollment Contractors (NPECs)) to enroll in and maintain their enrollment in the Medicare program. The surety bond requirements of § 424.57(d) have been in effect since 2009. DMEPOS suppliers presently are the only Medicare provider or supplier type required to submit and maintain a surety bond as a condition of enrollment.

Section 6402(g)(1) of the Affordable Care Act amended section 1834(a)(16) of the Act by adding a provision regarding the volume of DMEPOS billing as it relates to the surety bond requirement. Section 1834(a)(16)(B) of the Act now provides that a DMEPOS supplier must furnish a surety bond of at least $50,000 that the Secretary determines is commensurate with the volume of the supplier's billing. Consistent therewith, and as discussed further, we are proposing changes to § 424.57(d) to improve the overall surety bond process.

b. Issues with Existing § 424.57(d)

In general, a surety bond -- in the context of Medicare DMEPOS supplier enrollment -- represents a promise by a surety that it will pay CMS a certain sum amount if the DMEPOS supplier to whom the surety issued the bond fails to repay a debt it owes to CMS; these debts include overpayments, civil money penalties, and assessments. Indeed, debt recoupment is the principal goal of CMS' surety bond requirement. The bond requirement has other benefits, too. One is that it facilitates additional screening of the DMEPOS supplier beyond that performed under § 424.518(c). Before deciding whether to issue a surety bond, the surety reviews the finances and other aspects of the DMEPOS supplier that CMS may currently lack the means to assess. This is critical given the program integrity threats that DMEPOS suppliers pose. The other is that suppliers may learn that CMS has referred their unpaid debt to the surety. Concerned that the surety might cancel the supplier's bond if the surety has to pay the debt to CMS – leaving the supplier at risk of revocation if it is unbonded – the supplier finally pays the debt. Since 2012, in fact, two of CMS' DME Medicare Administrative Contractor (MAC) jurisdictions have collected a combined $171.3 million in DMEPOS supplier payments in this manner. Hence, § 424.57(d) is not only a means of collection from sureties but also from the suppliers themselves.

Over the years, though, our surety bond collection efforts have encountered challenges. A particular difficulty has been that sureties sometimes do not make payment to CMS notwithstanding their obligation to do so under both § 424.57(d) and the surety bond's terms. To

illustrate, of the approximately $32 million in DMEPOS supplier debts that CMS referred to sureties for payment between CY 2016 and CY 2018, CMS collected only $2.85 million from the sureties.[141] To help address this issue, we proposed in a March 1, 2016, provider enrollment rule that CMS could reject an enrolling or enrolled DMEPOS supplier's surety bond if the surety that issued the bond failed to make a required payment to CMS pursuant to § 424.57(d).[142] Though we did not finalize this provision, the problem remains very serious. To illustrate:

- CMS data from 2025 showed that a combined $37.5 million in DMEPOS supplier debts had been referred to seven sureties for payment. The sureties collectively paid only $540,000. Although the affected suppliers paid about $5.5 million of the $37.5 million amount once their debts were referred to the sureties, it is extremely disconcerting that the sureties – despite their obligation to do so under the bond's terms – paid no more than 1.5 percent of the amount of debt referred to them.

- The two previous-referenced DME MAC jurisdictions also informed CMS that since 2012 they have referred a combined $229.2 million in DMEPOS supplier debts to sureties. Of this total, sureties paid only $35.7 million.

In sum, sureties' failures to make required payments to CMS have resulted in hundreds of millions of dollars in unpaid DMEPOS supplier debts. Sureties should not be able to avoid fulfilling their legal and financial obligations to CMS. Given the resulting harm to American taxpayers and the need to protect the Trust Funds, we propose the following changes to § 424.57(d).

c. "Sufficient Evidence" Standard and Review of Overpayment Calculations

Section 424.57(d)(5)(i) states that the DMEPOS surety bond must guarantee that the surety will -- within 30 days of receiving written notice from CMS containing "sufficient

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[141] The remainder (which could not be collected) was referred to the Department of Treasury consistent with existing CMS procedures.

[142] Medicare, Medicaid, and Children's Health Insurance Programs; Program Integrity Enhancements to the Provider Enrollment Process" (81 FR 10720).

evidence" to establish the surety's liability under the bond of unpaid claims, civil money penalties (CMPs), or assessments -- pay CMS a total of up to the full penal amount of the bond. Section 424.57(a) defines "sufficient evidence" as documents CMS may supply to the surety to establish that the supplier had received Medicare funds exceeding the amount due and payable under the statute and regulations, the amount of a CMP, or the amount of some other assessment against the DMEPOS supplier.

One reason a surety sometimes cites for refusing to pay CMS is that, in the surety's view, CMS did not furnish "sufficient evidence" that the surety is, in fact, liable for payment. This, in many cases, is incorrect, and there have been numerous instances where no matter how many documents CMS furnishes to the surety that conclusively establish the supplier's debt and the surety's obligation, the surety continuously – and, we believe, inappropriately -- maintains that the evidence is insufficient. Nonetheless, and to clarify its scope, we propose to revise the "sufficient evidence" definition such that the term would mean that CMS has furnished documentation to the surety that establishes all of the following:

- The amount and basis of the overpayment, CMP, or assessment that the DMEPOS supplier owes.
- That it is an unpaid claim.
- A valid surety bond exists.
- The request to the surety for payment satisfies the surety bond requirements, specifically:

++ When a bond is in effect, that the unpaid claim, CMP, or assessment occurred during the term of the bond. This includes when a DMEPOS supplier changes its surety during the term of a bond; or

++ When the DMEPOS supplier fails to furnish a bond, submit a rider[143] when required,

[143] Section 424.57(a) defines "rider" as a notice issued by a surety that a change in the bond has occurred or will occur.

or if the DMEPOS supplier's billing privileges are revoked, that the unpaid claims, CMPs, or assessments are asserted or imposed against the DMEPOS supplier during the 2 years following, and they are based on overpayments or other events that took place during the term of the bond or rider.

This clarification is not intended to change which surety is responsible when a DMEPOS supplier obtains a bond from a new surety; in that circumstance, 42 CFR 424.57(d)(9) determines which surety is responsible. Rather, we believe these revisions would remove any ambiguity about the surety's responsibility to make payment to CMS, and we expect sureties to do precisely this after receipt of this documentation.

In addition, some sureties have declined to make required payments to CMS because: (1) CMS did not furnish documentation to the surety as to how CMS calculated the overpayment, CMP, or assessment; or (2) the supplier's appeal rights regarding the overpayment have not been exhausted. This is improper because neither the existing definition of "sufficient evidence" nor any other provision in current § 424.57(d) (including paragraph (d)'s required bond terms) have ever required such documentation or the exhaustion of appeal rights. Regarding the former, "sufficient evidence" only requires documentation "that the DMEPOS supplier had received Medicare funds in excess of the amount due and payable under the statute and regulations, the amount of a CMP, or the amount of some other assessment against the DMEPOS supplier." The surety's obligation under the bond to make payment is the critical consideration, not the details of how CMS calculated the debt amount. As for appeals, CMS in the aforementioned January 2, 2009, final rule -- in response to a public comment recommending that CMS not request surety payment before appeals are exhausted – was clear that: "We do not agree that we should be prohibited from seeking payment from a surety until all supplier appeals have been exhausted. In addition, we believe that it is appropriate for the surety to pay CMS a total of up to the full penal amount of the bond when sufficient evidence is presented."[144]

[144] 74 FR 174.

While the foregoing reflects longstanding policy, we propose to reiterate this by revising existing paragraph (d)(5)(ii). Said paragraph currently states that the surety bond "must provide the following: The surety is liable for unpaid claims, CMPs, or assessments that occur during the term of the bond." We propose to designate the clause beginning with "The surety is liable……." as new paragraph (d)(5)(ii)(A). New paragraphs (d)(5)(ii)(B) and (C) would require the bond to provide that:

- The surety agrees not to challenge or dispute the amount CMS determines is owed from the obligor, the underlying calculations, or the basis for overpayment.
- The surety must make payment to CMS as required under the bond and this paragraph (d) regardless of whether the obligor has available options to appeal, or pending appeals of, the overpayment, CMP, or assessment.

d. Decline to Accept Bonds from Noncompliant Sureties

Notwithstanding the aforementioned non-finalization of our surety bond rejection proposal in 2019, we maintain that CMS should not be required to accept bonds from non-compliant sureties. Again, the bond requirement's central purpose is to help CMS recoup monies it is owed. Sureties' failure to make required payments harms the Trust Funds and taxpayers, and CMS' continued acceptance of bonds from such sureties exacerbates said harm. Measures to hold such sureties accountable are therefore needed.

A non-exempt DMEPOS supplier must obtain and maintain a surety bond from an "authorized surety." The latter term is defined in part in § 424.57(a) as a surety "that has been issued a Certificate of Authority [COA] by the U.S. Department of the Treasury [DoT] as an acceptable surety on Federal bonds…". DoT is the principal overseer of processes involving surety companies that do business with the United States; indeed, 31 CFR 223.1(a) states that the regulations in 31 CFR Part 223 "govern the issuance, renewal, and revocation by the Secretary of the Treasury," acting through the DoT, Bureau of the Fiscal Service, of COAs "to bonding companies to do business with the United States as sureties on, or reinsurers of, Federal surety

bonds" under 31 U.S.C. 9304-9308 and Part 223, "and the acceptance of such obligations." COAs are addressed at 31 CFR 223.16. This regulatory provision states in part that a list of certificate holding companies is published annually in Department Circular No. 570 (Companies Holding Certificates of Authority as Acceptable Sureties on Federal Bonds and as Acceptable Reinsuring Companies). Per 31 CFR 223.17(a), a bond underwritten by a certified company on the 31 CFR 223.16 Department Circular No. 570 list may be presented to any agency-bond approving official for acceptance, and such agency bond-approving official may accept such bonds. To furnish DMEPOS surety bonds, a surety must be on this list as an acceptable surety.

Section 223.17(b)(1), though, states that an agency bond-approving official may decline to accept bonds underwritten by a certified company for cause if the company has been given advance written notice by said agency. The written notice must do all of the following:

- State the agency's intention to decline bonds underwritten by the company.
- State the reasons for or cause of the proposed declination of such bonds.
- Give the company an opportunity to rebut and to cure the stated reasons or cause.

Under section 223.17(b)(2), the agency may decline to accept the bonds if – after considering the company's submission under 223.17(b)(1) (or its failure to respond to the paragraph (b)(1) notice) – it issues a written determination that the bonds should not be accepted.

We believe section 223.17 is clear on its face that CMS may decline bonds in the circumstances described in said section. To this end, we propose to outline procedures for doing so in new § 424.57(d)(16). These procedures would include section 223.17(b)'s requirements (such as describing what qualifies as "for cause"), tailored to the specifics of the DMEPOS surety bond requirements.

In new § 424.57(d)(16)(i), we propose to mirror section 223.17(b)(2)'s language for purposes of consistency. We would state that CMS may decline to accept from an authorized surety any DMEPOS supplier surety bonds required under § 424.57(d) if: (i) the "for cause" standard in paragraph (d)(16)(ii) is met; and (2) the written notice and opportunity for rebuttal

requirements in paragraph (d)(16)(iii) are met.

In new § 424.57(d)(16)(ii), we propose that CMS' declination to accept DMEPOS surety bonds from a particular surety must be "for cause." For purposes of § 424.57(d)(16), "for cause" would involve circumstances "when a surety under paragraph (d) has not paid or satisfied an administratively final bond obligation" that is owed to CMS. This latter quoted language is in section 223.17(b)(2). Section 223.17(b)(3), meanwhile, states that the agency must define when a bond obligation becomes administratively final. We propose that this occurs when: (1) CMS has furnished "sufficient evidence" (as that term would be defined in our proposed revision thereto) to the surety of its obligation to make payment under the bond; and (2) the surety fails to make the required payment within 30 calendar days of receiving notice from CMS or its contractor to do so. This is consistent with current CMS practice.

New § 424.57(d)(16)(iii) would outline the procedures for furnishing written notice to the surety of our intention to decline to accept its DMEPOS supplier bonds. This paragraph would state that CMS sends, via certified mail, written notice to the surety of said intention. The notice must: (1) state the intention to decline bonds underwritten by the company; (2) list the reason(s) or cause for CMS' intention; (3) identify the instance(s) in which the surety failed to make the required payment(s); (4) describe the surety's rebuttal rights; and (5) provide the surety a 30-day opportunity to cure the stated reasons for declination. These requirements would help ensure that the surety received the notice and understands the basis for CMS' action.

In new § 424.57(d)(16)(iv), we propose a process by which the surety can rebut CMS' conclusions in the § 424.57(d)(16)(iii) notice it received. This process would be similar to rebuttals in § 424.541(b) for stays of enrollment and in § 424.546 for enrollment deactivations. This approach is appropriate for three reasons. First, it has been used for many years in provider enrollment and the processes are well-established. It can hence be expeditiously expanded to include surety rebuttals. Second, section 223.17 specifically uses the term "rebut" as opposed to "appeal" or "reconsideration"; the latter two terms represent processes addressed in 42 CFR Part

498. Using a rebuttal process for section § 424.57(d)(16)(iv) would accordingly be consistent with section 223.17's "rebut" terminology. Third, our existing rebuttal process for enrollment affords providers and suppliers ample opportunity to be heard. We believe the same would hold true for sureties.

In paragraph (d)(16)(iv)(A)(*1*), we propose that when a surety receives the notice specified in (d)(16)(iii), the surety has 30 calendar days from the date of the notice to submit a rebuttal to CMS' intention to decline to accept DMEPOS surety bonds from the surety. Although the rebuttal timeframe for stay and deactivation rebuttals is 15 days, we believe 30 days is appropriate for sureties since this process would presumably be new to them.

In paragraph (d)(16)(iv)(A*)(2),* we propose that CMS may, at its discretion, extend the 30-day time-period referenced in paragraph (d)(16)(iv)(A)*(1).*

In paragraphs (d)(16)(iv)(B)(*1*) through (*4*), we propose that the rebuttal must meet all of the following:

- Be in writing.
- Specify the facts or issues about which the surety disagrees with CMS' intention to decline to accept bonds.
- Submit all documentation the surety wants CMS to consider in its review of the rebuttal.
- Be submitted in the form of a letter that is signed and dated by:

++ The surety's chief executive officer, chief operating officer, general partner, or equivalent official who is a W-2 employee of the surety with the authority to legally and financially bind the surety to Federal and State laws; or

++ A representative (as defined in § 498.10). If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the surety; this statement is sufficient to constitute notice of such authority. If the legal representative is not an attorney, the surety must file with CMS written notice of the appointment of a representative;

this notice of appointment must be signed and dated by, as applicable, the official in the previous paragraph or a legal representative.

In paragraph (d)(16)(iv)(C), we propose that the surety's failure to submit a rebuttal that is both timely under paragraph (d)(16)(iv)(A) and fully compliant with all of paragraph (d)(16)(iv)(B)'s requirements constitutes a waiver of all rebuttal rights under this section. If the surety fails to timely submit a compliant rebuttal, CMS would issue a subsequent written determination that it will not accept bonds underwritten by the surety and state the declination's effective date, which would not be before the date of this written determination.

In paragraph (d)(16)(iv)(D), we propose that upon receipt of a timely and compliant rebuttal, CMS reviews the rebuttal to determine whether to proceed with its intended declination of surety bonds from the surety.

In paragraph (d)(16)(iv)(E), we propose that after its receipt of any timely and compliant rebuttal, CMS notifies the surety in writing of the following--

- Its review of the rebuttal;
- Its decision as to whether to proceed with its intended declination to accept DMEPOS surety bonds from the surety and the basis for that decision; and
- Any such declination's effective date, which would not be before the date of the notice described in paragraph (d)(16)(iv)(E).

Although enrollment stays and deactivations can be implemented and become effective before the stay or deactivation letter is sent to the provider, we wish to give the surety an opportunity to submit the rebuttal and for CMS to consider it before deciding whether to proceed with any declination. We also believe this approach is more consistent with section 223.17(b) than one that would permit declination before CMS' completes its review of the rebuttal. In addition, a determination made under paragraph (d)(iv)(E) is not an initial determination under § 498.3(b), and, therefore, is not appealable.

Under new paragraph (d)(16)(v)(A), and as previously indicated, the surety would have a

30-day opportunity to remedy the issues leading to CMS' intention to decline to accept the surety's bonds. CMS would have the discretion to extend this 30-day period.

Under new paragraph (d)(16)(v)(B), we propose the following:

- The surety, within the required timeframe, would have to submit written proof that it has cured all the deficiencies in question. This proof could include, for example, documentation that it has fully paid or satisfied all outstanding financial obligations forming the bases of CMS' intended declination. It would not be enough for the surety to merely state that it has cured the stated reasons or cause.

- CMS would decide whether the submitted written proof is adequate and whether all deficiencies have been corrected. If the surety submitted a timely and compliant rebuttal, CMS would include its decision on the cure matter in the rebuttal decision letter described in proposed (d)(16)(v)(A). If the surety does not submit a timely and complete rebuttal, CMS would include its decision on the cure issue in a final letter to the surety confirming whether CMS will decline to accept surety bonds issued by the surety.

In paragraph (d)(16)(vi)(A), and consistent with 31 CFR 223.17(b)(4), we propose to maintain a list of sureties from which CMS would not accept DMEPOS surety bonds under paragraph (d)(16). This list would be made public on CMS' website and updated as needed so that DMEPOS suppliers understand which sureties they may and may not use for purposes of the surety bond requirement.

In paragraph (d)(16)(vi)(B), we propose that CMS may, in its discretion, at any time remove a surety from the list described in paragraph (d)(16)(vi). CMS would notify the surety in writing of said removal and the effective date thereof. This would give CMS flexibility to again accept bonds from the surety should, in CMS' judgment, circumstances warrant.

2. Medicare DMEPOS Supplier Relationship Reporting

A significant challenge CMS has faced in stemming DMEPOS fraud, waste, and abuse has been our lack of upfront knowledge of certain outside entities with which the supplier may

have business relationships. While DMEPOS suppliers have for decades been required to report on the Form CMS-855S their 5 percent or greater owners, general and limited partners, managing employees and organizations, and corporate officers and directors, the supplier need not disclose various other parties with which they are associated, such as the following:

- Marketing companies, which perform services for the supplier such as advertising, mail and e-mail solicitation to beneficiaries, and generating leads.
- Wholesalers that purchase supplies from manufacturers and then sell them to the supplier.
- Fulfillment companies, which generally are entities with which the supplier contracts to deliver items to beneficiaries (rather than the supplier directly delivering them).

Considering the excessive program integrity risk DMEPOS suppliers have long posed and the need to ensure that the products they distribute to beneficiaries are quality items, we believe we must understand the full chain of the supplier's acquisition and eventual distribution and delivery of these goods. Without knowing, for instance, the entity from which the supplier purchased its products, we may lack important information to help us ascertain the seller's credentials. Indeed, we have seen instances where certain wholesalers distribute low-quality supplies that can harm beneficiaries, sometimes with the knowledge of questionable DMEPOS suppliers seeking to limit costs at the expense of patient care. In a similar context, it can be difficult for us to verify whether a supplier will properly deliver supplies to beneficiaries if we do not know whether the supplier uses a fulfillment company for this function and, if it does, which company. Some fulfillment entities may have poor records regarding supply delivery (with beneficiaries sometimes never receiving needed items) or have participated in fraud schemes.

Awareness of these companies' identities would help CMS: (1) safeguard beneficiaries; (2) validate the supplier's compliance with the enrollment standards in § 424.57(c); (3) vet these entities for program integrity risks; and (4) ascertain whether the supplier may be acting with other entities in a larger fraud scheme, an especially important consideration given that we have

seen an alarming number of such instances over the years. We also note that some of these entities may have as much (or more) involvement with the supplier's regular operations as certain parties that must currently be reported, such as indirect owners and various members of boards of directors. This, in our view, further warrants the collection of data about wholesalers and fulfillment companies.

Marketing entities are of particular concern to us. Section 424.57(c)(11) currently states that – with three exceptions outlined in § 424.57(c)(11)(i) through (iii) – suppliers may not contact a beneficiary by telephone when supplying a Medicare-covered item. This also applies to companies with which the supplier contracts to perform marketing services on the supplier's behalf. Some suppliers have used marketing entities to convince beneficiaries that they need certain DMEPOS items when, in fact, they do not. There have been instances where a marketing company cold-calls Medicare beneficiaries to obtain their personal data (sometimes promising the beneficiary free items in return); it will then use this information to: (1) prepare orders for certain DMEPOS items; and (2) pay physicians to sign them regardless of whether the patient requested the product. The following reports and cases – some of which were outlined earlier in the cited CY 2026 Home Health Prospective Payment System (HH PPS) proposed rule (90 FR 29108) – are illustrative of this behavior:

- A May 2024 OIG report stated that Medicare paid for off-the-shelf braces marketed to beneficiaries by telemarketers using prohibited direct solicitation.[145]

- Also in May 2024, a Florida man was sentenced to 96 months in prison for his role in a DMEPOS kickback scheme. He and others owned and operated marketing call centers and telemedicine companies through which they secured physicians' orders for DMEPOS for Medicare beneficiaries without regard to medical necessity.[146]

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[145] "Medicare Remains Vulnerable to Fraud, Waste, and Abuse Related to Off-the-Shelf Orthotic Braces, Which May Result in Improper Payments and Impact the Health of Enrollees" (A-09-21-03019).

[146] *https://www.justice.gov/usao-nj/pr/florida-man-sentenced-96-months-prison-role-multimillion-dollar-health-care-kickback.*

● A California woman was sentenced in December 2023 to 15 years in prison for billing Medicare for over $24 million by submitting fraudulent claims for medically unnecessary DME – mostly power wheelchairs (PWC) – and PWC repairs. As the *de facto* owner of two DMEPOS supplier companies (both of which were Medicare-enrolled in the names of her out-of-state relatives), the individual orchestrated a scheme in which she paid marketers for patient referrals and then directed them to take patients to physicians, who prescribed medically unnecessary DME (including PWCs) that her companies used to submit fraudulent claims to Medicare.[147]

● In September 2023, a Federal district court entered a judgment against a Virginia DMEPOS supplier for damages and penalties under the False Claims Act for over $12 million. In its complaint filed in district court, the United States alleged that over a nearly 6-year period, Medicare paid the supplier over $600,000 for medical braces furnished to Medicare beneficiaries related to DMEPOS prescriptions that the supplier illegally purchased from marketing companies. The DMEPOS supplier paid a fee for each prescription that it purchased and then used these prescriptions (along with personal and medical data provided by the marketing companies) to submit 923 fraudulent Medicare claims.[148]

● A Georgia woman pled guilty in June 2024 to an information charging her with conspiracy to commit health care fraud. The individual and her conspirators owned, operated, and had a financial interest in DMEPOS companies through which they obtained physicians' orders for DMEPOS for Medicare beneficiaries without regard to medical necessity. They obtained the DMEPOS orders using marketing call centers and telemedicine companies, caused the submission of false and fraudulent Medicare claims, and paid illegal kickbacks.[149]

● A South Carolina man was sentenced to 9 years in prison in March 2024 for his role in a nearly $100 million healthcare fraud scheme. The individual controlled and operated at least

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[147] https://www.justice.gov/usao-cdca/pr/redondo-beach-woman-sentenced-15-years-prison-leading-24-million-scam-billed-medicare.
[148] https://www.justice.gov/usao-edva/pr/virginia-medical-equipment-provider-ordered-pay-12-m-medicare-fraud-scheme-civil.
[149] https://www.justice.gov/usao-nj/pr/georgia-chiropractor-admits-149-million-health-care-fraud-and-kickback-scheme-related.

10 DMEPOS companies located throughout the United States. The companies entered into agreements with an offshore, advertised call center to purchase physicians' orders so the DMEPOS companies could bill Medicare. When a Medicare beneficiary called the applicable number, the beneficiary would be screened for eligibility and then convinced that the beneficiary needed a brace and oftentimes upsold on other braces. The call center would then contact a telemedicine company whose physician or nurse practitioner would issue a prescription without regard to the medical necessity. Beneficiaries were prescribed braces without ever being examined by, seeing, or, in some instances, even speaking to a medical professional.[150]

- A Texas man in March 2026 was sentenced to 150 months in prison for organizing and leading a $61.5 million health care fraud and wire fraud conspiracy in which thousands of Medicare beneficiaries who were the victims of deceptive telemarketing were sent thousands of orthotic braces, foot baths, and genetic tests they did not need. The defendant – who owned seven DMEPOS supply companies - owned a marketing company, too. Working with an offshore call center located in the Philippines, the defendant and others peddled medically unnecessary orthotic braces, foot baths, and genetic tests to Medicare beneficiaries nationwide. In audio recordings presented at trial, the defendant was heard pressuring beneficiaries to accept these products even after the beneficiaries protested that they did not need or want them.[151]

- A Mississippi man who owned a marketing company and was the beneficial owner of eight DMEPOS companies was sentenced in May 2026 to 196 months in prison for his role in a scheme to bilk Medicare (and another Federal health program) out of nearly $200 million by selling patient information and sham doctors' orders for orthotic braces that patients did not want or need. According to court documents and evidence presented at trial, the defendant worked with overseas telemarketing call centers that pressured elderly Americans to provide their

[150] https://www.justice.gov/usao-sc/pr/mt-pleasant-man-sentenced-nine-years-federal-prison-role-one-largest-medicare-fraud.
[151] https://www.justice.gov/opa/pr/texas-fugitive-apprehended-and-sentenced-over-12-years-prison-61m-telemarketing-fraud-scheme.

personal and health insurance information and agree to accept medically unnecessary orthotic braces; in certain instances, the call centers altered call recordings to make it seem like Medicare patients agreed to the braces when they did not.[152]

As we have noted in prior provider enrollment rules, our goal is to stop fraud before it begins and to depart from the "pay and chase" model, whereby we take action only after the fraud commences. The earlier we learn of any marketing companies (domestic or foreign) the supplier uses, the sooner we can screen them and determine whether they present payment safeguard threats to the Medicare program.

In light of all these concerns, we propose the following provisions.

First, new § 424.57(i) would require all DMEPOS suppliers to report on the Form CMS-855S application (or its successor form), in a complete and accurate manner (including any documentation requested by CMS under § 424.510(d)(2)(iii)(C) to verify or explain the furnished information), all domestic and foreign entities and individuals that do any of the following:

- Perform any marketing service of any type for the supplier.
- Furnish DMEPOS items or services to beneficiaries on the supplier's behalf, such as fulfillment companies.
- Are wholesalers from which the supplier purchases DMEPOS items for provision to the supplier's beneficiaries.

CMS would revise the Form CMS-855S via a separate Paperwork Reduction Act (PRA) package to collect this data. Stakeholders may submit comments on these form revisions during the eventual PRA notice-and-comment process.

Second, we propose in new §§ 424.530(a)(26) and 424.535(a)(31) that we may deny or revoke the DMEPOS supplier's enrollment if CMS determines that any entity or individual reported pursuant to § 424.57(i) -- or the relationship or business arrangement the entity or

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[152] *https://www.justice.gov/opa/pr/former-nfl-player-sentenced-over-16-years-prison-197m-medicare-fraud.*

individual has with the supplier – poses an undue risk of fraud, waste, or abuse, or of beneficiary harm. This provision would give us the ability and flexibility to address program integrity threats based on the reported information. However, CMS would not deny or revoke enrollment under these provisions as a matter of course but only when justified after carefully considering the facts and circumstances. We also propose that the effective date of a revocation under § 424.535(a)(31) would be the date on which CMS determines that a supplier should be revoked pursuant to § 424.535(a)(31). This would conform to CMS' proposal in the CY 2027 HH PPS proposed rule (placed on display at the **Federal Register** on July 1, 2026 (91 FR 41216))[153] to make all of our revocation effective dates retroactive rather than keep some of them prospective (that is, effective 30 days after the date on which the revocation letter is mailed to the provider). As that proposed rule would designate all revocation effective dates therein as § 424.535(g)(1)(i) through (xxvi), we propose that § 424.535(a)(31)'s effective date would be designated as new § 424.535(g)(1)(xxxi).

3. Beneficiary Consent for Items

An especially disturbing DMEPOS supplier practice over the years has been the shipping of supplies to beneficiaries without the latter having requested them, followed by the supplier billing Medicare for the items. Indeed, we have seen fraud schemes involving stolen beneficiary information, which enables the supplier to report a beneficiary's data on the claim with a fictitious diagnosis and date of service and a random referring provider's information; in some cases, the supplier never even sent the item to the beneficiary. The following are several recent examples of this conduct (as noted previously, we generally use the term "supplier" to refer to DMEPOS suppliers and the term "provider" to refer to other provider and supplier types):

- A supplier submitted approximately a dozen claims for items it claimed to have sent to various beneficiaries. All of the beneficiaries: (1) denied the diagnoses the supplier reported;

[153] "Calendar Year 2027 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the Expanded HH Value-Based Purchasing Model; and Other Medicare and Medicaid Policies".

(2) confirmed that they never received the items; and (3) denied knowing the supplier or the referring provider.

- A beneficiary received orthotics from a supplier via shipment. The beneficiary stated that he did not know why he received the items, and that the reported diagnosis was incorrect. While he stated that he was scheduled for an appointment with the reported referring provider, he had not yet seen said provider.

- A beneficiary received a call from a party identifying itself as Medicare, advising her that she would receive orthotics for free. The beneficiary informed the caller that she did not need them, but she ultimately received the supplies. The beneficiary later told CMS that she never saw or spoke with the referring provider and had never used the services of the supplier listed on the claim.

- Another beneficiary received a call from a supplier: (1) asking her questions about her medical diagnosis; and (2) stating that she was qualified to receive DMEPOS items at no cost to her. She received the items but informed CMS that she had neither requested nor needed them; she also had never discussed needing the items with her primary care provider.

We believe that requiring prior confirmation from the beneficiary that the item was requested and needed before it is sent to the beneficiary would help stem this improper activity. Suppliers could not simply send unauthorized items to patients and receive payment for them. To this end, we propose an additional DMEPOS supplier standard in new § 424.57(c)(32) that would require DMEPOS suppliers to have a process for obtaining prior beneficiary consent for items the supplier sends to the beneficiary at their home or residence. For purposes of this standard:

- The standard only applies to the initial order the supplier receives, not to refills.

- The process must, at a minimum, include the following:

++ After receiving a valid order for the item from the ordering or prescribing provider (for example, physician), the supplier must telephone or e-mail the beneficiary (or, if applicable,

their representative (such as a caretaker or guardian)) and ask whether the beneficiary or representative: (1) is aware of the order or prescription; (2) whether the beneficiary needs the item; and (3) consents to receiving the item. The item cannot be delivered until these three conditions are met, even if the beneficiary or representative cannot be reached. If only the representative can satisfy the requirements, the supplier's process must include a means of confirming that said individual is authorized to act on the beneficiary's behalf.

++ For each such item, the supplier must document in a written log: (1) the beneficiary's or representative's name and either their phone number or e-mail address (whichever means of communication was used); (2) time(s) and date(s) of the contact(s); and (3) a statement that the three conditions were met.

We solicit comments on any additional minimum requirements that should be included in this process.

4. Surveys and Accreditations

Section 424.58(e)(8)(i)(A) states that a DMEPOS accreditation organization (AO) must perform a survey of all DMEPOS supplier locations for which the supplier seeks accreditation or reaccreditation with the AO. (This includes, but is not limited to, accreditations: (i) for a new item type the supplier has not previously furnished; or (ii) as required under § 424.551.) Surveys help determine whether the supplier meets the DMEPOS quality standards. These standards address matters such as: (1) administration; (2) financial, human resources, and information management; (3) equipment and item delivery and set-up; (4) patient and caregiver training and instruction; and (5) patient follow-up. The standards are both extensive and detailed because of the need to confirm the supplier's legitimacy. Compliance with the quality standards is necessary for the supplier to enroll in Medicare.[154]

Given the importance of DMEPOS supplier surveys in protecting beneficiaries and

[154] The quality standards can be found at https://www.cms.gov/research-statistics-data-and-systems/monitoring-programs/medicare-ffs-compliance-programs/downloads/final-dmepos-quality-standards-eff-01-09-2018.pdf.

facilitating program integrity, the following proposed changes to § 424.58(e)(8)(i)(A) would expand the instances in which a survey must be performed.

First, § 424.551 states that a DMEPOS supplier undergoing a CIMO -- which is defined as an individual or organization acquiring more than a 50 percent direct ownership interest in the supplier within 36 months of its initial enrollment (or within 36 months of its most recent CIMO) -- must enroll as a new DMEPOS supplier, undergo a survey, and obtain a new accreditation. There are three supplier exceptions to this "36-month rule" in § 424.551: (1) the supplier's parent company is undergoing an internal corporate restructuring; (2) the supplier's owners are changing the supplier's business structure, and the owners remain the same; and (3) an individual owner of the supplier dies. We are concerned that the lack of a supplier survey in these three exempted situations -- as well as with suppliers that undergo CIMOs beyond the 36-month window – leaves CMS unable to confirm whether the supplier under its new majority ownership is compliant with the quality standards and is committed to patient care. To us, the central issues are the change in the supplier's controlling interest itself and the potential involvement of the new majority owner(s) -- rather than the timing (for instance, more than 36 months after initial enrollment) or whether an exception applies.

We therefore propose to revise § 424.58(e)(8)(i)(A) such that any DMEPOS supplier in which an individual or organization acquires more than a 50 percent direct ownership interest requires a survey. This survey requirement would thus apply a modified version of the definition of CIMO in § 424.551(a); that is, it would apply even if the CIMO: (1) occurred more than 36 months after initial enrollment or the supplier's most recent CIMO; or (2) qualifies for an exception under § 424.551(c). We note that this change would only involve the performance of a survey. A supplier undergoing a CIMO that is excepted or occurs outside the 36-month period would not have to enroll as a new supplier or receive a new accreditation based solely on the CIMO.

Second, we propose to also include practice location changes within § 424.58(e)(8)(i)(A).

If a supplier moves to another site, we have no means of ascertaining whether it is compliant with the quality standards in that new physical environment. To illustrate, several standards pertain to personnel qualifications. Since the new location may result in new employees, we must ensure that said personnel meet, for instance, licensure or certification requirements. Accordingly, we believe this proposed revision is needed to help safeguard beneficiaries.

Regarding paragraph structure, new § 424.58(e)(8)(i)(A)*(1)* and *(2)* would include the situations currently described in § 424.58(e)(8)(i)(A) as well as our two proposed new scenarios.

5. Ordering Unnecessary DMEPOS Services or Items

Several of the criminal cases cited earlier – as well as other criminal cases and situations we have seen – involve physicians ordering DMEPOS services and items that were either not reasonable or not necessary. This is sometimes done as part of a fraud scheme, with the physician receiving remuneration from the supplier that will be providing the services and items. Millions of Medicare dollars are at risk from such behavior. While we have various means of addressing these situations, a significant program integrity gap remains; specifically, our existing authority to immediately revoke the physician is limited in certain circumstances. To illustrate, under § 424.535(a)(8)(i) and (a)(21), respectively, we can revoke:

- A provider or supplier that submits a claim or claims for services that could not have been furnished to a specific individual on the date of service.

- A physician or eligible professional who has a pattern or practice of ordering, certifying, referring, or prescribing Medicare Part A or B services, items, or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements.

In our aforementioned scenario, though, § 424.535(a)(8)(i) could only apply to the DMEPOS supplier (that is, the supplier submitting the claim), not to the doctor who ordered the item (Dr. X). While § 424.535(a)(21) could apply to Dr. X as the ordering physician, it may require multiple instances of Dr. X's non-compliant ordering. This effectively means we might

have to wait until Dr. X engages in this behavior a second or third time (or more) before we can take revocation action, thus allowing Dr. X to continue said misconduct and threaten the Trust Funds. This would run counter to our obligation to protect taxpayer dollars and, equally important, Medicare beneficiaries from unnecessary and potentially dangerous services and items. We must be able to take swift action on the physician's enrollment. We thus propose in new § 424.535(a)(29) that CMS have the authority to revoke a physician's or practitioner's enrollment if the individual ordered a DMEPOS item or service that was not reasonable or not necessary. The revocation effective date under proposed new § 424.535(g)(1)(xxix) would be the date on which CMS determines that the supplier should be revoked under § 424.535(a)(29).

We stress that this proposed revocation ground is not restricted to demonstrated DMEPOS fraud schemes. No prior finding of fraud would be required. On the other hand, stakeholders should not assume that CMS intends to revoke every physician or practitioner who orders a DMEPOS service or item that is later determined not to be reasonable or necessary. CMS would only take revocation action when, after careful consideration of the facts and circumstances, said action is warranted. In addition, § 424.535(a)(29) would be limited to the ordering of DMEPOS items or services, in large part because of the longstanding program integrity threat that DMEPOS suppliers have posed – higher, perhaps, than any other Medicare provider or supplier type.

C. Factors for Consideration for Denial and Revocation Decisions

As already alluded to, CMS under § 424.535(a) may revoke a provider's enrollment for any reason specified in that paragraph. These reasons include, for instance, the provider's: (i) failure to adhere to Medicare enrollment requirements; (ii) exclusion by the HHS OIG; (iii) felony conviction within the previous 10 years; (iv) pattern of improper or abusive billing; and (v) termination by another Federal health care program. A revocation helps safeguard the Medicare program, the Trust Funds, and beneficiaries by removing (and preventing payment to) Medicare providers that have engaged in problematic or otherwise non-compliant behavior.

When a provider is revoked, it is generally barred from reenrolling in Medicare for a period of 1 to 10 years. The length of this "reenrollment bar" is determined based upon the severity of the basis of the revocation.

CMS also has reasons in § 424.530(a) for which it can deny a provider's enrollment application, some of which duplicate our revocation grounds in § 424.535(a) (for instance, OIG exclusion). The general rationale for a denial mirrors that for a revocation: to protect the Medicare program and its beneficiaries from potentially fraudulent or abusive activity.

For several of our denial and revocation grounds, CMS in its determination must consider various criteria outlined within the applicable denial/revocation reason in §§ 424.530 and 424.535. As an example, § 424.535(a)(9) permits revocation if the provider fails to report a change in their enrollment information (such as a change in practice location) within the required timeframe. Section 424.535(a)(9)(i) through (iv) lists the following factors that CMS must consider in its decision: (i) whether the data in question was reported; (ii) if the data was reported, how belatedly; (iii) the data's materiality; and (iv) any other information that CMS deems relevant to its determination.

Such specified criteria have, in our view, hindered CMS' denial and revocation authority – even to the point where we could not deny or revoke the provider in a particular instance even though CMS believed that it was justified under the circumstances. Consider these two § 424.535(a)(9) scenarios:

Scenario 1 - A provider was required to report a certain change to us within 30 days but did not do so until Day 50.

Scenario 2 - A supplier failed to report a change involving information that, on the surface, might not appear as crucial as that in Scenario 1.

Revocation might prove challenging in both situations. In the former, the data was ultimately submitted 20 days after the deadline. This may weigh against a revocation per § 424.535(a)(9)(i) and (ii) – even if the information was material. The end result could be

incorrect payments being made to the provider due to the lack of timely, updated information. For Scenario 2, an apparent lack of materiality per § 424.535(a)(9)(iii) could, in some circumstances, override the failure to disclose the change.

We outlined our concerns regarding factors in the aforementioned CY 2027 HH PPS proposed rule (91 FR 72022). One particular concern we discussed involved the criterion in several of our denial and revocation grounds that requires CMS to consider whether the provider has any history of final adverse actions as defined in § 424.502 (such as felony convictions). We stated that most aberrant billing we have seen is done by providers with no history of adverse actions. Yet the adverse action factor essentially requires us to weigh against a denial or revocation for such providers. It aids non-compliant providers so long as the provider lacks an adverse history (which it often will), hence obstructing our program integrity efforts.

The point is that the facts of every potential denial and revocation case are very different. We must accordingly have the maximum possible flexibility to address them without criteria that might effectively compel us to enroll (or maintain the enrollment of) a non-compliant provider – something that could seriously harm the Trust Funds, the taxpayers, and beneficiaries.

We proposed in the CY 2027 HH PPS proposed rule to remove the factors in § 424.535(a)(8)(ii) and § 424.530(f) (the latter addresses reapplication bars). Given the scope of the foregoing problem, though, we believe we must go much further and remove all factors from our denial and revocation reasons. Our proposed regulatory revisions would be as follows:

- In § 424.530(a)(6)(ii)(C), deleting--

++ The second sentence of the opening paragraph.

++ Paragraphs *(1)* through *(5)*.

- In § 424.530(a)(7), deleting paragraphs (iii), (iii)(A), (iii)(B), and (iii)(C).
- In § 424.530(a)(12), deleting--

++ The second sentence of the opening paragraph.

++ Paragraphs (i) through (v).

- In § 424.530(a)(14), deleting--

++ The second sentence of paragraph (i).

++ Paragraphs (i)(A) through (C).

- In § 424.530(a)(15), deleting--

++ The second sentence of paragraph (i).

++ Paragraphs (i)(A) through (E);

++ Paragraphs (i)(C)*(1)* through *(3).*

- In § 424.530(a)(17)--

++ Deleting paragraphs (ii) and (ii)(A) through (F).

++ Redesignating paragraph (i) as the only sentence in (a)(17).

- In § 424.535(a)(9), deleting--

++ The second sentence of paragraph (a)(9)'s opening paragraph.

++ Paragraphs (i) through (iv).

- In § 424.535(a)(12), deleting--

++ The second sentence of paragraph (a)(12)(i)'s opening paragraph.

++ Paragraphs (a)(12)(i)(A) through (C).

- In § 424.535(a)(14)--

++ Revising (a)(14)'s opening paragraph to read: "CMS determines that the physician or eligible professional has a pattern or practice of prescribing Medicare-covered drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries or both, or fails to meet Medicare requirements."

++ Deleting paragraphs (i), (i)(A) through (H), (ii), and (ii)(A) through (C).

- In § 424.535(a)(15)--

++ Deleting paragraphs (ii) and (ii)(A) through (F).

++ Redesignating paragraph (i) as paragraph (a)(15)'s only sentence.

- In § 424.535(a)(17), deleting--

++ The second sentence of paragraph (a)(17)(i)'s opening paragraph.

++ Paragraphs (a)(17)(i)(A) through (F).

● In § 424.535(a)(18), deleting--

++ The second sentence of paragraph (a)(18)'s opening paragraph.

++ Paragraphs (a)(18)(i) through (v).

● In § 424.535(a)(20), deleting--

++ The second sentence of paragraph (a)(20)'s opening paragraph.

++ Paragraphs (a)(20)(i) through (vii).

● In § 424.535(a)(21), deleting--

++ The second sentence of paragraph (a)(21)'s opening paragraph.

++ Paragraphs (a)(21)(i) through (ix).

● In § 424.535(a)(22), deleting--

++ The second sentence of paragraph (a)(22)(i)'s opening paragraph.

++ Paragraphs (a)(22)(i)(A) through (E).

++ Paragraphs (a)(22)(i)(C)(*1*) through (*5*).

● In § 424.535(c)(3), which lists factors for consideration in determining the reenrollment bar length for a provider's second revocation, deleting--

++ The second sentence of paragraph (c)(3)'s opening paragraph.

++ Paragraphs (c)(3)(i) through (iv).

● In § 424.535(i)--

++ Deleting paragraphs (i)(2) and (i)(2)(i) through (iv).

++ Redesignating paragraph (i)(1) as the only sentence in paragraph (i).

● In § 424.535(j)--

++ The second sentence of paragraph (j)'s opening paragraph.

++ Paragraphs (j)(1)(i) through (iv).

D. Faster Enrollment Change Reporting for Medicare Providers

Providers must report changes to their enrollment data within the timeframes specified in our regulations. DMEPOS suppliers under § 424.57(c)(2) must disclose all such changes within 30 days of the change. All other provider and supplier types must report changes within 30 days or 90 days, depending on the data involved. Changes in ownership, practice location, and final adverse actions are typically subject to a 30-day timeframe, with 90 days for most others.

We propose to require that all changes of information – regardless of the type of data involved or the provider or supplier type – be reported within 30 days. While ownership, practice location, and final adverse action changes are important (hence their general 30-day timeframes), other data changes are, too. A failure to timely report a new managing employee or corporate officer, for example, could result in CMS unknowingly paying a provider with a high-level official who poses a program integrity risk based on past or current conduct. Too, if we do not timely learn of a provider's new bank, billing agency, doing business as name, or correspondence address, CMS risks sending funds or information to -- or receiving claims from – the wrong entity or individual; this could lead to incorrect payments or the inadvertent release of confidential data. In short, any outdated or erroneous enrollment information can threaten the Trust Funds, making, in our view, a 90-day reporting period much too long. We believe that a shorter, across-the-board reporting timeframe would help ensure more accurate data. It would also eliminate uncertainty as to whether a particular data element is subject to the 30-day period or, instead, the 90-day period. We note that DMEPOS suppliers are well-accustomed to the 30-day period, and we believe all other provider and supplier types will also become accustomed; this has been our past experience when we have reduced certain reporting timeframes from 90 to 30 days.

This proposal does not mean that CMS now intends to revoke every provider that fails to meet these reporting timeframes. Our authority to revoke enrollment under § 424.535(a)(9) for failing to timely report changed data is discretionary (not mandatory), and we sometimes use

other vehicles to address failures to timely disclose changes, such as stays of enrollment under § 424.541 and deactivations under § 424.540.

Our specific regulatory revisions are as follows:

In § 410.33(g)(2), which pertains to independent diagnostic testing facilities, we propose to delete the existing second and third sentences. The new second sentence would state that all changes in enrollment information must be reported within 30 days of the change.

In § 424.205(c)(5), which addresses Medicare diabetes prevention programs, we would remove the current language and state that all changes in enrollment information must be reported within 30 days of the change.

Sections 424.516(d)(1), (d)(2), (e), (e)(1) and (e)(2) address reporting requirements for other provider and supplier types. We propose to delete all these paragraphs and revise § 424.516(d)'s lone sentence such that all changes in enrollment information must be reported within 30 days of the change. We would also change the title of paragraph (d) from "Reporting requirements for physicians, nonphysician practitioners, and physician and nonphysician practitioner organizations" to "Reporting requirements for all other provider and supplier types".

Section 424.516(e)(3) addresses requirements for ambulance suppliers to report license or certification revocations or suspensions. We propose to re-designate paragraphs (e)(3), (e)(3)(i), and (e)(3)(ii) as new paragraphs (e), (e)(1), and (e)(2), respectively. In addition, we would change paragraph (e)'s title from "Reporting requirements for all other providers and suppliers" to "Special air ambulance supplier reporting requirements."

E. New Bases for Medicare Provider Enrollment Denial/Revocation

1. CY 2027 HH PPS Proposed Rule Grounds

Among the denial and revocation reasons we proposed in the CY 2027 HH PPS proposed rule were the following--

- Proposed new § 424.535(a)(24) would permit CMS to revoke enrollment if the provider's or supplier's enrollment presents a high risk of fraud, waste, or abuse due to the

provider's or supplier's location within a limited geographic area that has an excessive number of providers and suppliers.

- Proposed new § 424.530(a)(19) would allow denial of enrollment if the provider's or supplier's practice location is in the same suite or office as another provider or supplier whose Medicare enrollment has been revoked or denied under § 424.535 or § 424.530.

- Proposed new § 424.530(a)(20) would permit denial of a hospice's enrollment if any of the following apply--

++ The hospice's medical director: (1) is the medical director of multiple other hospices; or (2) practices at such a distance (for example, in a different State) from the enrolling hospice that the medical director cannot realistically perform all medical director functions required under 42 CFR part 418.

++ The hospice's administrator: (1) is the administrator of multiple other hospices; or (2) practices at such a distance (for example, in a different State) from the enrolling hospice that the administrator cannot realistically perform all administrator functions required under 42 CFR part 418.

++ The hospice's medical director does not have an active physician medical license in the State in which they are practicing.

We explained at great length in the proposed rule the reasons for these provisions and briefly summarize them here.

Regarding proposed § 424.535(a)(24), we noted the alarming increase in situations where numerous providers and suppliers – sometimes of the same type – are simultaneously operating within a very small geographic area (for instance, a multi-block sector), the same complex or building, or even the same office. We cited as examples: (1) 18 HHAs operating within the same building in Columbus, Ohio; and (2) hundreds of HHAs and hospices having enrolled in Los Angeles County over the span of several years. There was no medical need for such increases, which were entirely out of proportion with any increase in the region's beneficiary population

and could be a strong indicator of fraud. As for proposed § 424.530(a)(19), sharing a suite or office with a provider who has been deemed non-compliant with Medicare enrollment requirements could spur concerns about the newly enrolling provider's own willingness to maintain compliance if enrolled. This is particularly true when – in cases we have seen -- several providers in the same suite engage (or seek to engage) in a fraud scheme, have their Medicare enrollments revoked or denied, and another provider aims to enroll in that same office. Proposed § 424.530(a)(20), meanwhile, reflected the longstanding program integrity issues involving hospices. Of special concern were instances where an individual is a medical director or administrator of numerous hospices, sometimes at a great distance from the hospice location. This raises questions as to whether such persons are actually fulfilling these roles consistent with our regulations.

We recognized in the proposed rule – and do so again here – that some of these situations do not automatically mean fraud, waste, and abuse is occurring. Many medical facilities and complexes have a large number of providers and suppliers located therein. For example, a medical center comprising of three adjacent buildings may have seven physician practices with different specialties, two laboratories, etc.; some neighborhoods may have several types of providers and suppliers within them. Too, a physician operating in the same suite as a revoked provider is not automatically indicative of fraud. Nevertheless, some of the fraud schemes we have encountered have similarities to the situations addressed in these three proposed provisions. Considering the hundreds of millions of taxpayer dollars that such schemes can threaten, we need the discretion to deny or revoke providers and suppliers in the three proposed circumstances if warranted. So concerned are we about such situations that we believe these three denial or revocation grounds should be both denial and revocation bases, rather than only a denial reason or only a revocation reason (for instance, the § 424.535(a)(24) scenario only permits revocation).

Thus, we propose the following provisions. First, proposed new § 424.530(a)(23) would permit denial in the circumstances described in § 424.535(a)(24) in the July 1, 2026, proposed

rule. Second, proposed new revocation grounds in § 424.535(a)(26) and (27) would duplicate the §§ 424.530(a)(19) and (20) denial grounds in the July 1, 2026, proposed rule. Third, the effective dates of proposed new § 424.535(a)(26) and (27) would, under proposed new § 424.535(g)(1)(xxxiii) and (xxvii) be the date on which CMS determines that the provider should be revoked under these paragraphs; said date would align with our previously mentioned proposal in the CY 2027 HH PPS to make the remainder of our prospective revocation grounds retroactive.

2. Change in Hospice Administrators

We have already noted in the present and the CY 2027 HH PPS proposed rules the serious program integrity risks posed by hospices in recent years. Among the hospice fraud schemes we have seen involves administrators opening clusters of hospices within a small geographic area -- sometimes even in the same building – without any corresponding need for such an increase in hospice services. The administrator inappropriately bills Medicare through these hospices, departs the hospices, and then repeats the pattern as administrator of other hospices the individual opens. Even if the administrator does not start up the hospices, the person may engage in misconduct at several hospices, and his or her successors as administrator may do the same. Constant changes of administrators can raise questions as to the hospice's legitimacy and stability and, more importantly, whether the provider is engaged in fraud, waste, or abuse.

While we acknowledge that administrators may depart hospices for entirely legitimate reasons (for example, retirement, taking a different position, etc.), we must protect the Medicare program against situations where the administrator turnover reflects improper conduct. We hence propose in new §§ 424.530(a)(24) and 424.535(a)(28) to have the authority to deny or revoke a hospice's enrollment if the hospice changes its administrator within 36 months following the hospice's initial enrollment or its most recent change in administrator. The revocation effective date under § 424.535(g)(1)(xxviii) would be the date on which CMS

determines that the hospice should be revoked under § 424.535(a)(28). We emphasize that our proposal would not represent an across-the-board prohibition against administrator changes within 36 months, for, again, we recognize that many such changes have no nefarious intent. It would simply afford us the authority to take measures should the situation warrant it.

3. Denial and/or Revocation of Old and New Owner in Ownership Changes

We earlier referenced § 424.551, which requires DMEPOS suppliers to enroll as a new supplier and obtain a survey and accreditation if they undergo a non-exempt CIMO. A similar 36-month CIMO provision is in § 424.550(b)(1) for hospices and HHAs. The main purposes of this "36-month rule" are twofold. First, it helps prevent "flipping", whereby a provider enrolls in Medicare after receiving a survey and/or accreditation and then promptly sells the business to another party such that the latter need not receive a survey/accreditation. This makes it harder for CMS to confirm that the provider under its new ownership meets all Medicare requirements. Second, and even if "flipping" is not involved, the 36-month rule enables CMS to fully scrutinize the provider and the new owner via the initial enrollment and survey/accreditation processes.

Considering the failures of some providers to comply with the 36-month rule as well as efforts to circumvent it (such as by concealing the ownership change from CMS), we proposed in the CY 2027 HH PPS proposed rule to give CMS the authority to deny or revoke enrollment under §§ 424.530(a)(22) or 424.535(a)(25) if the provider does not comply with the provisions of, as applicable, § 424.550(b)(1) or § 424.551. Yet other ownership changes – depending on their particular facts -- can at times pose program integrity risks, such as: (1) HHA, hospice, and DMEPOS supplier CIMOs occurring outside the 36-month period; and (2) CIMOs involving provider types that are not subject to a 36-month rule (such as skilled nursing facilities). Of considerable concern to us are situations where the owner of a provider that presents serious program integrity risks attempts to sell the business to another party, perhaps as part of a larger fraud operation. The following examples are illustrative:

Example 1 - U owns Ambulance Supplier V, which has 20 employees. V was recently reactivated after having been deactivated for non-compliance with enrollment requirements. Both U and V are now under investigation for potential fraud. U decides to sell the company to W, who has previously been revoked from Medicare and intends to change V's name but retain its employees. A Form CMS-855B enrollment application is submitted to report the planned sale, though the sale is not scheduled to occur for another 60 days.

Example 2 - X has owned Hospice Y for 5 years (outside of § 424.550(b)'s 36-month window). X sells Y to Z, but neither X nor Z report the sale to CMS, in violation of the requirement to report ownership changes within 30 days. X thus remains on record with CMS as the owner even though Z is the actual owner.

Both scenarios are disconcerting. In the first: (i) U might be selling V in hopes that doing so would end the investigation of U's activities; and (ii) the company – which remains under investigation -- is being sold to a party with a prior revocation. In the second, the failure to report means that Medicare monies may be going to an entity whose new owner has not been vetted by CMS -- at potentially significant risk to the Medicare program. The apparent risks that U, V, and W (for W, based on its prior revocation) pose and the non-compliance of X and Z raise serious questions as to whether any of them can be relied upon as current or future partners of the Medicare program. Since neither of these two situations is directly covered by §§ 424.550(b) or 424.551, we believe additional safeguards are needed to address problematic ownership changes. We accordingly propose the following in new § 424.536.

In paragraph (a), we propose that CMS, as applicable to the situation, may deny or revoke the enrollment of any provider or supplier involved in a change in majority ownership if CMS determines that the--

- The seller, buyer, or any provider or supplier involved in the change in majority ownership failed to comply with Medicare enrollment requirements; or
- The change in majority ownership, the seller, the buyer, or any provider or supplier

involved in the change of majority ownership poses an undue risk of fraud, waste, and abuse to the Medicare program.

Using our two examples, CMS could revoke V's enrollment due to U's attempt to forestall the investigation into U's activities if CMS determines this presents an undue fraud, waste, or abuse risk; if the sale of the business to W proceeds and W tries to reenroll V, CMS could deny the enrollment on the same "undue risk" basis. Regarding the second, neither the seller nor the buyer reported the change. This means that Y's enrollment could be revoked. Too, if Z tries to reenroll Y, CMS could deny the enrollment: (1) because Medicare requirements involving the CIMO were not met; and/or (ii) if CMS determines that an undue risk exists.

We recognize that previously proposed §§ 424.530(a)(22) and 424.535(a)(25) – as well as existing § 424.535(a)(9), which permits revocation for failing to timely report changes in ownership – may address some problematic CIMO situations. Yet proposed § 424.536 would go further in two ways. First, and unlike §§ 424.530(a)(22) and 424.535(a)(25), it would cover all CIMOs regardless of the provider or supplier type or the sale's timing. Second, denial or revocation under § 424.536 would be permitted based on an undue risk of fraud, waste, and abuse. Section 424.536 would hence enable CMS to address a greater number of circumstances surrounding a CIMO, although CMS could still utilize §§ 424.530(a)(22), 424.535(a)(9), or 424.535(a)(25) in lieu of or in conjunction with § 424.536 if the conditions for invoking any of the three former provisions exist.

In new § 424.536(b), we propose that paragraph (a) could be applied regardless of whether the provider's or supplier's name, identity, or location changes due to the CIMO. While CIMOs are sometimes accompanied by such changes, this does not negate the risk or non-compliance involved. Indeed, if we exempted § 424.536's application if the buyer changed the entity's name or identity, buyers might do precisely this to avoid a § 424.536 revocation. This concern of ours is why a number of our current denial and revocation reasons permit revocation under any of the provider's current or former names, numerical identifiers, or business identities.

In paragraph (c), we propose that a CIMO under § 424.536 occurs when a party acquires more than a 50 percent direct ownership interest in a provider (including via the cumulative effect of asset sales, stock transfers, consolidations, or mergers); this comports with the general CIMO definition in § 424.502. However, and consistent with our prior discussion, a § 424.536 CIMO could take place regardless of the provider type involved (for example, ambulance suppliers, HHAs), whether the CIMO occurred within 36 months of initial enrollment or the most recent CIMO, or whether the change in majority ownership requires a new, initial enrollment.

In paragraph (d), we propose that nothing in § 424.536 would negate the requirement that an HHA, hospice, or DMEPOS supplier enroll as a new provider or supplier and be surveyed/accredited if §§ 424.550(b) or 424.551 applies. This would merely remind stakeholders that the latter two provisions are separate and distinct from proposed § 424.536's denial and revocation authority.

Sections 424.530 and 424.535 contain procedures for denials and revocations (in addition to the denial and revocation grounds listed in §§ 424.530(a) and 424.535(a)). These procedures include, for example, reapplication and reenrollment bars, revocation effective dates, and specifications for submitting claims for services furnished before a revocation. To ensure these procedures apply to § 424.536 actions – that is, to directly tie § 424.536 to §§ 424.530 and 424.535, we propose to add new §§ 424.530(a)(27) and § 424.535(a)(32) by which CMS could deny or revoke under § 424.530 or § 424.535 if it determines that denial or revocation (as applicable) is warranted under § 424.536; the revocation effective date per new § 424.535(g)(1)(xxxii) would be the date on which CMS determines that the provider should be revoked under § 424.535(a)(32). Due to the breadth of § 424.536's provisions (such as its distinct definition of change in majority ownership), we believe our proposed approach is sounder than including all of § 424.536 within § 424.530 and § 424.535.

4. Other Improper Activity

Section 424.535(a)(7) permits revocation if the provider knowingly sells to or allows another individual or entity to use its billing number. (This does not include providers or suppliers who enter into a valid § 424.80 reassignment of benefits or a § 489.18 change of ownership.) While this provision has existed for many years, we have long been concerned about its narrowness. It only addresses a specific, unique scenario without capturing other very concerning situations directly or indirectly related to the provider's improper use of its enrollment, billing number, electronic funds transfer (EFT) arrangement, or other aspect of its relationship with Medicare. For example, there have been instances where an enrolled provider secures access to Medicare Beneficiary Identifiers and sells them to outside parties for nefarious purposes. Yet no existing revocation reason explicitly addresses such behavior. We believe § 424.535(a)(7) must be expanded to incorporate a wider range of inappropriate conduct. We thus propose to revise this paragraph to permit revocation if the provider engages in improper activity related to its Medicare enrollment, any billing number or identifier, or EFT arrangement. We would also change the paragraph title from "Misuse of billing number" to simply "Improper activity." (For purposes of § 424.535(a)(7), the term "improper" would have its plain language meaning.) In addition, the § 424.535(a)(7) effective date would be that which we proposed in the CY 2027 HH PPS proposed rule at revised § 424.535(g)(1)(vii) – namely, the date on which the conduct resulting in the revocation occurred.

We acknowledge that this is a broad expansion of § 424.535(a)(7). We do not intend for this provision to supplant other current revocation grounds addressing inappropriate conduct (for example, abusive or non-compliant prescribing under § 424.535(a)(14)). In fact, we expect to utilize revised § 424.535(a)(7) only in exceptional circumstances. Nonetheless, the vast array of potential scenarios involving such conduct requires that we close all regulatory gaps that could permit the provider to remain enrolled and continue its behavior, hence the need for § 424.535(a)(7).

F. Verification of Identity and Risk Posed by Foreign and Domestic Owners and Managing Employees

Although CMS has means of validating the identities of enrolling physicians, enrolling practitioners, and an organizational provider's individual owners and managing employees, such means are mostly limited to reviewing the individual's legal name and social security number (SSN) against the Social Security Number Verification Service (SSNVN). This presents two significant problems.

One is that we have seen a disturbing increase in Medicare provider identity theft. Unscrupulous individuals and entities have attempted to: (1) enroll in and bill Medicare using the SSNs (and other identifiers) of bona fide physicians and practitioners; and (2) shield their actual (and problematic) owners and managing employees by instead listing on the Form CMS-855 application the stolen identities of other persons as their owning and managing individuals. This has in certain instances permitted nefarious parties to enroll in Medicare – either directly or through an organization in which the party is the actual owner – and commit fraud because CMS' identity verification vehicles are limited.

The second dilemma is that providers sometimes list foreign owners and managing employees/organizations on the Form CMS-855. While there is no existing Medicare provider enrollment prohibition against a provider having a foreign owning or managing party, validation of the party's identity becomes difficult if no SSN or tax identification number (TIN) is included as many foreign parties lack one. The foreign status of such parties also makes it hard to confirm their specific location and any adverse legal history the party has (such as a criminal conviction or sanction). All this, in turn, can leave us unable to ascertain whether said foreign party poses a program integrity risk to Medicare – a vital consideration given the Medicare fraud schemes we have seen involving foreign nationals. Accordingly, although we are not seeking to bar foreign ownership or management of Medicare providers at this time, we still must strive to prevent potential threats to Medicare.

We believe the foregoing situations require that CMS have additional means of validating domestic and foreign identities and of reviewing possible risks posed by such parties. We hence propose the following regulatory revisions.

First, § 424.510(d)(2) outlines documentation that providers must submit as part of the enrollment process. Paragraph (d)(2)(ii) addresses documents that may be needed to uniquely identify the provider (though specific types of documents are not listed). To ensure our ability to verify the provider's identity and other data beyond what we currently require (such as the IRS CP-575 for TINs and legal business names), we propose the following:

- A new provision in paragraph (d)(2)(ii) by which CMS could require an individual provider, owner, managing employee, general or limited partner, or corporate officer or director to submit a copy of their driver's license, passport, social security card, birth certificate, or similar documentation if CMS determines it is needed to validate their identity. We emphasize that we would not ask for any of these documents as a matter of course but only if: (1) other verification means are unsuccessful; or (2) we suspect a possible case of identity theft. The overwhelming majority of providers would not have to submit them.

- To revise paragraph (d)(2)(iii), which permits CMS to require any other documentation needed to validate the data on the enrollment application, including, but not limited to, "documentation regarding the provider's or supplier's ownership or management." In paragraph (C) thereof, we would insert "domestic or foreign" between "provider's or supplier's" and "ownership." This would supplement our change to paragraph (d)(2)(ii) by reiterating our ability to request any documentation needed to validate ownership or management, including foreign.

Second, we propose in new §§ 424.530(a)(25) and 424.535(a)(30) that we may deny or revoke a provider's enrollment if the provider has a domestic or foreign owner, managing employee, managing organization, general or limited partner, or corporate officer or director: (1) whose identity or location cannot be confirmed; or (2) that CMS determines poses an undue risk

of fraud, waste, or abuse to Medicare. An example of such a risk might be that the foreign party is based in a nation in which other persons and entities have been (or suspected to have been) involved in Federal health care program (including Medicare) fraud -- though we emphasize that there are other factual scenarios in which an undue risk could arise, including with respect to domestic owners, managers, etc., as well as situations not involving identity verification. To a degree, our proposal is similar to existing §§ 424.530(a)(13) and 424.535(a)(19), albeit perhaps with a greater emphasis on risks posed by owners and managers themselves than on affiliations involving those parties. Indeed, it would be somewhat illogical to permit denial or revocation based on affiliations but not on individual threats that the parties in those relationships might present.

The effective date of a § 424.535(a)(30) revocation would, under § 424.535(g)(1)(xxx), be the date on which CMS determines that the provider should be revoked under this paragraph.

G. Medicaid and CHIP Provider Enrollment Reforms

As previously described, the Medicaid program (title XIX of the Act) is a joint Federal and State health care program that covers approximately 67 million low income-individuals. States have considerable flexibility when administering their Medicaid programs within a broad Federal framework, and programs vary from State to State. CHIP (title XXI of the Act) is a joint Federal and State health care program that provides health care coverage to over 7 million children in families with incomes too high to qualify for Medicaid, but too low to afford private coverage.

In operating Medicaid and CHIP, and as required by sections 1902(a)(78) and 2107(e)(1)(D) of the Act, respectively, each State requires providers to enroll in order to furnish, order, prescribe, refer, or certify eligibility for Medicaid or CHIP items or services in that State.[155] States may also establish their own provider enrollment requirements, which must be

[155] Section 1902(kk)(7) of the Act also requires physicians and other eligible professionals who order or refer Medicaid services and items to be enrolled in Medicaid. This requirement is made applicable to CHIP via section 2107(e)(1)(G) of the Act.

met in addition to the applicable Federal provider enrollment requirements. Similar to Medicare provider enrollment, the purposes of the Medicaid and CHIP provider enrollment processes are to ensure that providers: (1) meet all Medicaid or CHIP requirements (and any other State-specific or Federal requirements); (2) are qualified to furnish, order, prescribe, refer, or certify Medicaid and CHIP services, items, and drugs; and (3) are eligible to receive payment, where applicable.

Different States may have different provider enrollment processes in operating their Medicaid and CHIP programs. However, all States must comply with Federal Medicaid and CHIP provider enrollment statutory and regulatory requirements, including those in part 455, subparts B and E.[156]

1. Principal Purposes of Medicaid and CHIP Provider Enrollment Proposals

There are several key reasons for our proposed Medicaid and CHIP provider enrollment revisions in this proposed rule.

First, we have not updated part 455's provider enrollment provisions in a comprehensive, wide-ranging fashion since the previously noted February 2, 2011, final rule. As certain enrollment terminology and requirements have become outdated or otherwise need enhancement given this long passage of time, we believe revisions to part 455 are warranted

Second, the February 2, 2011, final rule emphasized the value of consistency between programs by establishing, for all three programs, common provider enrollment screening levels (limited, moderate and high) and application fee requirements. We also in that rule based other new Medicaid enrollment provisions partly on our stated desire for greater conformity to Medicare enrollment requirements. This included, for example, § 455.104(b)(1)(ii), in which we required disclosing entities, fiscal agents, and managed care entities to disclose the date of birth (DOB) and social security number (SSN) of any person with an ownership or control interest in the entity. (We similarly require owning and managing individuals of Medicare providers and

[156] All of subpart E, and 42 CFR 455.107 in Subpart B, are applicable to CHIP in accordance with §457.990.

suppliers to disclose their DOBs and SSNs.)

Various statutory provisions also emphasize consistency among programs. For example, under section 1902(kk)(3) of the Act, States must require providers to comply with the same requirements regarding disclosure of certain affiliations that also apply to Medicare under section 1866(j)(5) of the Act. Section 2107(e)(1) of the Act, meanwhile, makes the requirements of section 1902(kk) of the Act – including the screening, enrollment, and disclosure requirements – applicable to CHIP.

Yet the issue is not merely consistency between Medicare and Medicaid/CHIP. As already noted, and while all States must comply with the enrollment provisions in part 455, States often have different State-based Medicaid and CHIP provider enrollment requirements and processes. This can prove challenging for providers located in multiple States, for this could necessitate adherence to different requirements for many different State programs. We believe that harmonizing certain requirements via updates to part 455 could ease the burden on providers enrolling in (or enrolled in) multiple States' Medicaid programs and CHIPs. We emphasize, though, that our revisions are not intended to remove the States' traditional and general discretion over the requirements and operations of these programs.

Third, we believe it is critical to provide States with further means of preventing and combating potential and actual fraud, waste, and abuse. We presently have numerous grounds for which we can deny or revoke a Medicare provider's enrollment under §§ 424.530 and 424.535, respectively. These grounds address a broader range of circumstances than the Medicaid and CHIP denial and termination reasons specified at § 455.416. While some States may have State-specific denial and termination grounds beyond those in § 455.416, we are uncertain whether they adequately cover the many situations that could justify taking denial or termination action against a provider. To help States address such cases and protect Medicaid and CHIP monies and beneficiaries, we are proposing additional grounds for the State to deny or terminate a provider's Medicaid or CHIP enrollment, most of which mirror the existing Medicare

grounds in §§ 424.530 and 424.535.

The proposed changes in section V.G. of this proposed rule are generally discussed in the numerical order of the applicable regulatory provision in part 455. Unless noted otherwise, all references to Medicaid (for example, "Medicaid provider enrollments") should be read to include CHIP.

2. Legal Authorities

Our principal authorities for our Medicaid and CHIP provider enrollment proposals are as follows:

- Section 1102 of the Act provides general authority for the Secretary to prescribe regulations for the efficient administration of the Medicaid program and CHIP.

- Section 1902(kk)(1), under which the State must comply with the process for screening providers and suppliers under this title, as established by the Secretary under section 1866(j)(2) of the Act.

- Section 1902(a)(27) of the Act provides general authority for the Secretary to require provider agreements under the Medicaid State Plans with every person or institution providing services under the State plan. Under these agreements, the Secretary may require information regarding any payments claimed by such person or institution for providing services under the State plan.

- Section 4313 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) amended sections 1124(a)(1) and 1124A of the Act to require disclosure of both the Employer Identification Number (EIN) and SSN of each provider or supplier, each person with an ownership or control interest in the provider or supplier, any subcontractor in which the provider or supplier directly or indirectly has a 5 percent or more ownership interest, and any managing employees, including directors and officers of corporations and non-profit organizations and charities.

● Section 2107(e) of the Act, which provides that certain title XIX and title XI provisions apply to States under title XXI.

3. Definitions (§§ 455.2 and 455.101)

We propose to: (1) revise several definitions in §§ 455.2 and 455.101 to clarify existing processes and enhance conformity to Medicare enrollment definitions; and (2) add several definitions to § 455.101.

a. "Conviction or Convicted"

The current definition of "Conviction or Convicted" in § 455.2 reads, "a judgment of conviction has been entered by a Federal, State, or local court, regardless of whether an appeal from that judgment is pending." We propose to change this to, "has the same meaning as the definition of 'convicted' in 42 CFR 1001.2." That definition states:

● A judgment of conviction has been entered against an individual or entity by a Federal, State or local court, regardless of whether--

++ There is a post-trial motion or an appeal pending; or

++ The judgment of conviction or other record relating to the criminal conduct has been expunged or otherwise removed.

● A Federal, State or local court has made a finding of guilt against an individual or entity;

● A Federal, State or local court has accepted a plea of guilty or nolo contendere by an individual or entity; or

● An individual or entity has entered into participation in a first offender, deferred adjudication, or other program or arrangement where judgment of conviction has been withheld.

We believe this definition is more detailed, thorough, and robust than that currently in § 455.2; it would accordingly provide greater clarity as to the types of convictions falling within § 455.2's purview. Moreover, we reference the § 1001.2 definition in §§ 424.530(a)(3) and 424.535(a)(3), which permit, respectively, denial or revocation of Medicare enrollment based on

a felony conviction. Since, as we discuss later, we are proposing similar felony provisions in this rule, we believe that a concomitant definition of "Conviction or Convicted" in part 455 is warranted.

b. Definitions Related to Disclosures

As later addressed in greater detail, a "disclosing entity" is required under § 455.104(b) to report certain information to the State. These data include but are not limited to:

- Any person (individual or corporation) with an ownership or control interest in the disclosing entity.
- Whether the person (individual or corporation) disclosed in the previous bullet is related to another person with an ownership or control interest in the disclosing entity as a spouse, parent, child, or sibling.
- Any other disclosing entity in which an owner of the disclosing entity has an ownership or control interest.
- Any managing employee of the disclosing entity.

A central purpose of this information is to help the State confirm that the provider is not under the direct or indirect control of an excluded party. Various definitions in current § 455.101 apply to this disclosure requirement. These include:

- *"Disclosing entity,"* which means "a Medicaid provider (other than an individual practitioner or group of practitioners), or a fiscal agent."
- *"Other disclosing entity,"* which means "any other Medicaid disclosing entity and any entity that does not participate in Medicaid but is required to disclose certain ownership and control information because of participation in any of the programs established under titles V, XVIII, or XX of the Act." This includes:--

++ Any hospital, skilled nursing facility, home health agency, independent clinical laboratory, renal disease facility, rural health clinic, or health maintenance organization that participates in Medicare (title XVIII of the Act);

++ Any Medicare intermediary or carrier; and

++ Any entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, health-related services for which it claims payment under any plan or program established under title V or title XX of the Act.

- *"Person with an ownership or control interest,"* which means a person or corporation that:

++ Has an ownership interest totaling 5 percent or more in a disclosing entity;

++ Has an indirect ownership interest equal to 5 percent or more in a disclosing entity;

++ Has a combination of direct and indirect ownership interests equal to 5 percent or more in a disclosing entity;

++ Owns an interest of 5 percent or more in any mortgage, deed of trust, note, or other obligation secured by the disclosing entity if that interest equals at least 5 percent of the value of the property or assets of the disclosing entity;

++ Is an officer or director of a disclosing entity that is organized as a corporation; or

++ Is a partner in a disclosing entity that is organized as a partnership.

We propose to revise or supplement several of these definitions as follows:

c. Addition of "Managing Organization"

We propose to add a definition of "managing organization" to § 455.101 that states: "Managing organization means an entity that exercises operational or managerial control over or that directly or indirectly conducts the day-to-day operations of a provider, either under contract or through some other arrangement." This definition, which mirrors § 424.502's definition of this term, would be used for our proposed requirement (discussed later) that providers furnish data on entities that manage them.

d. Revisions to the Definition of "Person with an Ownership or Control Interest"

The opening language of this definition states: "Person with an ownership or control interest means a person or corporation that…." We propose to change this to read: "Person or

organization with an ownership or control interest is one that…." We do not believe organizational interests should be limited to corporations; any organizational interest in a provider is pertinent regardless of whether it is a corporation, partnership, limited liability company, etc.

We are not proposing to concomitantly revise paragraph (e) of this definition, which includes officers and directors of disclosing entities that are corporations as "person[s] with an ownership or control interest". As previously noted, sections 1124 and 1124A of the Act require providers to disclose certain information about various persons and entities associated with the provider. Per section 1124(a)(3)(B) of the Act, this includes "officer[s] or [director[s] of the entity if the entity is organized as a corporation." To remain consistent with section 1124(a)(3)(B) of the Act, only officers and directors of corporations (rather than, for example, of limited liability companies) would fall within paragraph (e).

4. Expanded Medicaid and CHIP Provider Enrollment Disclosure Requirements

We propose the following changes to § 455.104:

- The current version of § 455.104(b)(1)(i) requires the disclosure of the name and address of any person (individual or corporation) with an ownership or control interest in the disclosing entity, fiscal agent, or managed care entity. The addresses for corporate entities must include (as applicable) the primary business address, every business location, and P.O. Box address. We propose two changes to this paragraph.

First, we would change the language that reads "any person (individual or corporation) with an ownership or control interest" to "any person or organization with an ownership or control interest." We believe that disclosures of owning or controlling organizations should be made irrespective of whether the entity is a corporation, partnership, limited liability company, or other form of organization. It is important that States can screen all owning and controlling parties for potential program integrity issues. Second, we propose to remove the word "corporate" from the second sentence of paragraph (b)(1)(i). This is to clarify that the addresses

of any organization under paragraph (b)(1), regardless of the entity's structure, must be disclosed.

- Section 455.104(b)(1)(iii) requires in part the disclosure of an "Other tax identification number (in the case of a corporation) with an ownership or control interest in the disclosing entity (or fiscal agent or managed care entity)…" We propose to change this to reference the tax identification number of any organization with an ownership or control interest in, or that serves as a managing organization of, the disclosing entity (or fiscal agent or managed care entity). This revision would: (1) accord with our proposed change to § 455.104(b)(1)(i) by removing the reference to corporations so that the paragraph applies to all organizations, regardless of type; and (2) add managing organizations to the paragraph's purview.

As we stated in the earlier noted September 10, 2019, final rule, a managing entity often has as much (or more) day-to-day control over a provider or supplier as an owner. Given the important roles that managing organizations have over providers' operations, we believe that States must know the organizations' identities to help ensure that Medicaid and CHIP program integrity is maintained. We note that Medicare providers and suppliers have long been required to disclose managing organizations as part of the enrollment process.

- Section 455.104(b)(2) generally requires disclosure of the identities of persons reported per paragraph (b)(1) who are related to each other. We propose to change the language "person (individual or corporation) with an ownership or control interest" in that paragraph to "person or organization with an ownership or control interest." This change would conform to our proposed revision of the definition of "person with an ownership or control interest" in § 455.101.

- Section 455.104(b)(4) requires the disclosure of "the name, address, date of birth, and Social Security Number of any managing employee of the disclosing entity (or fiscal agent or managed care entity)." We propose to redesignate this as new § 455.104(b)(4)(i) and to add new § 455.104(b)(4)(ii) to read: "The name, address, and tax identification number of any managing

organization of the disclosing entity (or fiscal agent or managed care entity)." This is consistent with our proposed revisions to § 455.104(b)(1) involving managing entities.

Meanwhile, paragraph (a) of § 455.106 states that before the Medicaid agency enters into or renews a provider agreement, or at any time upon written request by the Medicaid agency, the provider must disclose to the Medicaid agency the identity of any person who:

- Has ownership or control interest in the provider, or is an agent or managing employee of the provider (§ 455.106(a)(1)); and
- Has been convicted of a criminal offense related to that person's involvement in any program under Medicare, Medicaid, or the title XX services program since the inception of those programs (§ 455.106(a)(2)).

We propose to revise paragraph (a) to expand the types of adverse actions that must be reported to the State. We would require that before the State enters into or renews a provider agreement, or at any time upon written request by the State, the provider must identify whether the provider, any person or organization with an ownership or control interest in the provider, or any agent, managing employee or managing organization of the provider, under any current or former name, numerical identifier, or business identity--

- Was, within the preceding 10 years, convicted of a Federal or State felony offense (regardless of type);
- Has been revoked or terminated, or is currently suspended, from participation in any State Medicaid program, CHIP, Medicare, or any other Federal health care program;
- Is currently subject to a payment suspension under § 455.23 or under CHIP or Medicare; or
- Has had its health care license revoked -- or whose license is currently suspended -- in any State. (This includes situations where the individual or entity voluntarily surrendered the license in lieu of disciplinary action.)

These four actions would be included in revised paragraph (a)(1) and new paragraphs

(a)(3), (4), and (5). We also would expand existing paragraph (a)(2)'s scope to include misdemeanors involving sexual assault or financial misconduct; this is because we proposed in the CY 2027 HH PPS proposed rule to permit denial or revocation of a provider's enrollment based on a misdemeanor conviction involving sexual assault or financial misconduct.

There are two main reasons for this proposal. First, these data – some of which, in the Medicare context, must currently be reported on the applicable Medicare provider enrollment application (OMB Control No.: 0938-0685) -- would give States greater insight into potential program integrity threats that the disclosed party may pose. This, in turn, could further safeguard the Medicaid program, CHIP, and their beneficiaries. Second, and as already noted and discussed in more detail later, we are proposing a number of new Medicaid and CHIP provider enrollment denial and termination reasons. Since several of these grounds involve the reportable actions under proposed revised § 455.106(a), we believe this information would help the States determine whether a denial or termination is warranted.

We particularly note the proposed addition of the language "under any current or former name, numerical identifier, or business identity." This language has been used with several existing Medicare denial and revocation reasons in §§ 424.530 and 424.535 for a number of years. The purpose is to enable us to take action against problematic parties notwithstanding any identity change. We believe States must have the same ability. We do not believe a party's demonstrated program integrity risk disappears upon a mere change in name, especially when the entity or person makes this change to circumvent an existing adverse action. Indeed, we previously saw situations where a revoked Medicare provider changed its name to evade its revocation and subsequent bar against reenrolling in Medicare. In our view, the party's risk remains, and States must base their payment safeguard actions more on said risk than on the party's current name or identity.

Existing § 455.106(c) states that the Medicaid agency may refuse--

- To enter into or renew an agreement with a provider if any person who has an

ownership or control interest in the provider, or who is an agent or managing employee of the provider, has been convicted of a criminal offense related to that person's involvement in any program established under Medicare, Medicaid, or the title XX Services Program; or

- To enter into or may terminate a provider agreement if it determines that the provider did not fully and accurately make any disclosure required under § 455.106(a).

We propose to delete this paragraph because these and all other denial and termination reasons in subpart B would, per this proposed rule, be included in revised § 455.416. This would ensure that all denials and terminations are addressed in one section rather than split between multiple sections.

5. New Bases for Medicaid and CHIP Provider Enrollment Denial and Termination

a. Introduction

Pursuant to the Secretary's general authority under section 1102 of the Act to prescribe regulations for the efficient administration of the Medicaid program and CHIP, we are proposing a number of additional denial and termination reasons. Our proposed grounds would--

- Be mandatory, meaning the State (except as discussed in the next bullet) would be required to deny or terminate enrollment if the facts of the case fall within those covered by the applicable denial or termination reason; and

- Permit the State in most cases to forgo mandatory denial or termination if the State determines that the denial or termination would not be in the best interests of its Medicaid program or CHIP.

We recognize that virtually all of our Medicare denial and termination grounds are discretionary. Yet we believe that making our proposed Medicaid denial and termination reasons mandatory – with the best interests exception -- is advisable, in part because it would be consistent with the mandatory nature of (and best interests exceptions within) most of 42 CFR Part 455's existing denial and termination grounds. Moreover, and notwithstanding our desire for greater consistency between Medicare and State Medicaid provider enrollment programs, we

maintain that substantial conformity between States in how they interpret and carry out Part 455's denial and termination reasons is also important. Indeed, this was a principal consideration behind the aforementioned February 2, 2011, final rule's establishment of additional provider enrollment requirements in subparts B and E of Part 455. We believe that having consistent, uniform interpretations of Federal Medicaid provider enrollment provisions in Part 455 is preferable to inconsistent ones and would reduce provider uncertainty regarding the meaning of these requirements.

b. Listing of Current Denial and Termination Reasons in § 455.416

The following denial and termination reasons are in existing § 455.416:

- Under paragraph (a), the State must terminate the enrollment of any provider where any person with a 5 percent or greater direct or indirect ownership interest in the provider did not submit timely and accurate information and cooperate with any screening methods required under this subpart.

- Under paragraph (b), the State must deny or terminate enrollment if a person with a 5 percent or greater direct or indirect ownership interest in the provider has been convicted of a criminal offense related to that person's involvement with Medicare, Medicaid, or title XXI of the Act in the last 10 years.

- Under paragraph (c), the State must deny or terminate enrollment of any provider that is terminated under Medicare or under the Medicaid program or CHIP of any other State and is currently included in the termination database under § 455.417.

- Under paragraph (d), the State must deny or terminate enrollment if the provider or a person with an ownership or control interest or who is an agent or managing employee of the provider fails to submit timely or accurate information.

- Under paragraph (e), the State must deny or terminate enrollment if the provider, or any person with a 5 percent or greater direct or indirect ownership interest in the provider, fails to submit sets of fingerprints in a form and manner to be determined by the Medicaid agency

within 30 days of a CMS or State Medicaid agency request.

- Under paragraph (f), the State must deny or terminate enrollment if the provider fails to permit access to provider locations for any site visits under § 455.432.

- Under paragraphs (g)(1) and (2), the State may deny or terminate enrollment if CMS or the State Medicaid agency--

++ Determines that the provider has falsified any information provided on the application; or

++ Cannot verify the identity of any provider applicant.

Paragraphs (b), (d), (e) and (f) state, however, that the State is not required to deny or terminate enrollment if it determines that denial or termination of enrollment is not in the best interests of the Medicaid program, and the State documents that determination in writing.

Also, under § 455.107(g), the State must deny a provider's enrollment if it determines under § 455.107 that a particular affiliation (as that term is defined under § 455.101) poses an undue risk of fraud, waste, or abuse.

We are proposing to delete existing § 455.416(a) through (g). This is primarily because some of these provisions fall within the larger scope of our proposed grounds. To avoid duplication and confusion by having two separate reasons involving similar conduct, we would incorporate the existing grounds within the proposed ones to the maximum extent possible. Those current § 455.416 grounds not falling within one of our proposed reasons would remain in § 455.416, though under a different paragraph designation and, in some cases, with revisions.

To summarize, revised § 455.416 would include: (1) the incorporation of several existing provisions within our proposed reasons; (2) the retention of several existing grounds with modifications; (3) the transfer of several denial and termination reasons from §§ 455.104, 455.106, and 455.107 to § 455.416; and (4) the incorporation of a number of Medicare denial and revocation grounds into Medicaid within § 455.416, though in most cases with the former's required factors and discretionary application replaced by the "best interests" exception

referenced in current § 455.416.

c. Revised § 455.416

(1) Exclusion (§ 455.416)(a))

In paragraph (a), we propose that the State must deny or terminate enrollment if a provider, person or organization with an ownership or control interest in the provider, managing employee or managing organization or agent of the provider, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program of the provider, is either--

- Excluded from Medicare, Medicaid, and any other Federal health care program, as defined in § 1001.2 of this chapter, in accordance with section 1128, 1128A, 1156, 1842, 1862, 1867, or 1892 of the Act.

- Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or non-procurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA).

States are already required to deny Medicaid participation for: (1) certain exclusions under section 1128 of the Act; and (2) government-wide debarments in accordance with section 2455 of the Federal Acquisition Streamlining Act. However, there is no explicit regulatory provision in subparts B and E of part 455 to this effect. Proposed § 455.416(a), which mirrors §§ 424.530(a)(2) and 424.535(a)(2) regarding denials and revocations of Medicare enrollment based on an exclusion or debarment, would address this. Also, we propose to include in § 455.416(a) the language in § 424.530(a)(2)(ii) stating that the former would include individuals and organizations that are either W-2 employees or contracted individuals and organizations of the provider. We believe the risk from excluded or debarred parties is no less with contracted parties than with W-2 employees.

As this is a mandatory denial and revocation reason under §§ 424.530 and 424.535, and because States are generally prohibited from making payments to excluded (42 CFR

1001.1901(b)) or debarred (2 CFR 180.305(a), 2 CFR part 376) providers, revised § 455.416(a) would not contain the aforementioned "best interests" exception.

(2) Affiliation Posing Undue Risk (§ 455.416(b))

As mentioned previously, the State, in consultation with us, must under § 455.107(g) deny or terminate a provider's enrollment if it determines under § 455.107 that a particular affiliation poses an undue risk of fraud, waste, or abuse. To ensure that all denial and termination reasons are included within one section, we propose to delete § 455.107(g) and designate this provision as revised § 455.416(b). No "best interests" exception would be included, for none exists in current § 455.107(g) and because States should consider the best interests of their programs in making the determination as to whether a particular affiliation poses an "undue risk" of fraud, waste, or abuse.

As part of this change, existing § 455.107(h) would be redesignated as § 455.107(g).

(3) Medicare/Medicaid/CHIP Termination (§ 455.416(c))

We previously noted current § 455.416(c), which requires denial or termination based on a Medicare, Medicaid, or CHIP termination and the provider currently being in the termination database. We propose to retain this provision essentially as is, including its present paragraph designation and its existing lack of a "best interests" exception; we would , though, remove the now-unnecessary qualification that the requirement applies to terminations on or after January 1, 2011.

(4) Misdemeanor Conviction (§ 455.416(d))

We propose to redesignate existing § 455.416(b) (which addresses criminal offenses related to Medicare, Medicaid, or CHIP) as revised § 455.416(d), with the "best interests" caveat included. Yet we also propose two other changes to redesignated § 455.416(d):

- We would restrict this denial or termination reason to misdemeanor convictions. Since felony convictions would, as discussed shortly, be addressed elsewhere in § 455.416, paragraph (d)'s limitation to misdemeanors would help prevent overlap.

- In the CY 2027 HH PPS proposed rule, we proposed in new §§ 424.530(a)(16) and 424.535(a)(16) that CMS could deny or revoke enrollment if the provider or supplier—or any owner, managing employee, managing organization, officer, or director thereof—was convicted of a Federal or State misdemeanor related to sexual assault or financial misconduct within the past 10 years that CMS deems detrimental to the best interests of the Medicare program and its beneficiaries. We propose to add this reason to revised § 455.416(d). This would not only facilitate consistency with proposed new §§ 424.530(a)(16) and 424.535(a)(16) but also allow the State to take action against problematic parties beyond those currently addressed in § 455.416(b).

As with most other existing and proposed Medicaid enrollment denial and termination reasons in Part 455, redesignated § 455.416(d) would include the previously discussed "best interests" exception. Too, the misdemeanor conviction would have to be detrimental to the best interests of the Medicaid program or CHIP (rather than those of the Medicare program).

(5) General Non-Compliance (New § 455.416(e))

Sections 424.530(a)(1) and 424.535(a)(1) state in part that we may deny or revoke Medicare enrollment if the provider is not in compliance with the Medicare enrollment requirements in title 42 or in the enrollment application applicable for its provider or supplier type. We propose a similar reason in revised § 455.416(e) whereby the State must deny or terminate enrollment if the provider is non-compliant with any requirement described in subpart B or E of part 455, though it may utilize the "best interests" exception.

We recognize that there could be some overlap between revised § 455.416(e) and certain other § 455.416 provisions. To illustrate, some providers must submit sets of fingerprints as part of the enrollment process consistent with subpart 455, subpart E. Failure to do could result in denial under existing § 455.416(e). Yet this could also fall within the scope of revised § 455.416(e) due to the provider's non-compliance with subpart E. To avoid duplicative application, we also propose to include existing § 455.416(a), (d), (e), (f), and (g)(2) within

revised § 455.416(e) as examples of subpart B or E non-compliance; we would, though, combine existing paragraphs (a) and (e) due to their similarities. In addition, revised § 455.416(e) would effectively incorporate existing § 455.106(c)(2), which permits denial or termination if the provider fails to make a required disclosure under § 455.106(a).

(6) Felony Convictions (§ 455.416(f))

In revised paragraph (f), we would mirror the current Medicare denial and revocation reasons in §§ 424.530(a)(3) and 424.535(a)(3) regarding felony convictions. We propose that the State must deny or terminate enrollment if the provider, any person or organization with an ownership or control interest in the provider, or any managing employee or managing organization of the provider was, within the preceding 10 years, convicted (as that term is defined in § 1001.2) of a Federal or State felony offense that the State determines is detrimental to the best interests of its Medicaid program or CHIP and their beneficiaries. Offenses would include, but not be limited in scope or severity to—

- Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted;
- Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud and other similar crimes for which the individual was convicted;
- Any felony that placed the Medicaid program or CHIP or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct; and
- Any felony that would result in mandatory exclusion under section 1128(a) of the Act.

We have long believed that any felony conviction, regardless of the type, raises questions as to whether the provider can be a reliable participant in Medicare. We believe the same concern would apply in the Medicaid program or CHIP. States thus must do whatever possible to prevent unnecessary risks to Medicaid or CHIP and those programs' beneficiaries. Nonetheless, under our proposal the State would have discretion to determine what types of

convictions are "detrimental to the best interest of the Medicaid program or CHIP or their beneficiaries" and could utilize the "best interests" exception if it deems warranted.

(7) False or Misleading Information (§ 455.416(g))

Under existing § 455.416(g)(1), the State may deny Medicaid or CHIP enrollment if CMS or the State determines that the provider has falsified any information provided on the application. Per existing § 424.530(a)(4), we can deny Medicare enrollment if the provider or supplier has submitted false or misleading information on the enrollment application to gain enrollment in the Medicare program; offenders may be referred to the OIG for investigation and possible criminal, civil, or administrative sanctions.

We propose to redesignate § 455.416(g)(1) as revised § 455.416(g), combine it with § 424.530(a)(4)'s language, and add further clarification. Under revised § 455.416(g), the State must deny or terminate Medicaid or CHIP enrollment if the provider submits false or misleading information to (or omits information from) the Medicaid program or CHIP to gain or maintain enrollment.

We believe that providers submitting false or misleading data or omitting data to become or remain enrolled in Medicaid or CHIP potentially pose the same level of risk to these two programs as they do to Medicare. The language "in order to gain or maintain enrollment" is particularly important because it clarifies two aspects of existing practice in the Medicare context. First, the requirement to submit complete and truthful information is not restricted to initial applications but also applies to revalidations, changes of information, and all other application types. Our proposed inclusion of "maintain" (as opposed to merely gaining enrollment, which implies initial submissions) is therefore necessary; providers must always submit truthful and accurate information to Medicaid and CHIP. Second, we believe that any false, misleading, or omissive submission to Medicaid or CHIP —regardless of whether it was made via the enrollment application, supporting documentation, or otherwise—should constitute grounds for denial or termination. The specific format of submission, in our view, is less crucial

than the actual submission.

Under current § 455.416(g)(2), States may deny or terminate the provider's Medicaid or CHIP enrollment if CMS or the State Medicaid agency cannot verify the identity of any provider applicant. We propose to delete this provision because we would include it within the general "Non-compliance" category in § 455.416(e)(1)(iv)).

We note that while current paragraph (g)(1) is discretionary, we propose to make revised paragraph (g) mandatory (though with the "best interests" provision in proposed (g)(2)) to be consistent with most of our other proposed denial and termination grounds.

(8) Drug Enforcement Administration Certificates (§ 455.416(h))

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, and the Controlled Substances Import and Export Act, as amended, and collectively referred to as the Controlled Substances Act (CSA) (21 U.S.C. 801-971); the implementing regulations for these statutes are in 21 CFR parts 1300 through 1321. The CSA makes possession of authority under State law to dispense controlled substances a requirement for both obtaining and maintaining a DEA Certificate of Registration.

Sections 424.530(a)(11) and 424.535(a)(13) state, in part, that we may deny or revoke a physician's or eligible professional's Medicare enrollment if the individual's DEA Certificate of Registration to dispense a controlled substance is currently suspended or revoked or is surrendered in response to an order to show cause. We believe that a DEA Certificate of Registration to prescribe controlled substances is akin to a State's requirement that a physician or eligible professional be licensed or certified by the State to furnish health care services. The loss of the ability to prescribe drugs via a suspension or revocation of a DEA Certificate indicates that the physician or eligible professional may be misusing or abusing their authority to prescribe such substances.

Yet those concerns are not limited to Medicare. Improper prescribing activities can harm Medicaid and CHIP beneficiaries and program integrity as much as Medicare patients and

program integrity. Hence, we propose in new § 455.416(h) that a State must deny or terminate enrollment if the physician's or practitioner's DEA certificate is currently suspended or revoked or is surrendered in response to an order to show cause, with the "best interests" provision included. The only difference would involve our use in § 455.416(h) of "practitioner" instead of "eligible professional," since the former term is broader than 42 U.S.C. 1396b(t)(3)(B)'s somewhat narrow definition of the latter.

(9) Misuse of Enrollment (§ 455.416(i))

Under current § 424.535(a)(7), we may revoke Medicare enrollment if the provider or supplier knowingly sells to or allows another individual or entity to use its billing number. (This does not apply to providers or suppliers who enter into a valid reassignment of benefits as specified in § 424.80 or a change of ownership outlined in § 489.18.) This provision is meant to prevent providers from permitting others to utilize their Medicare enrollment. A provider's enrollment is restricted and unique to that provider. Each provider must individually meet and maintain compliance with the legal requirements specific to it and cannot use the credentials of other providers, suppliers, or other parties to do so. To permit another party to bill Medicare via the provider's enrollment would entirely undercut this principle; it could lead to fraudulent individuals and entities (or other parties that Medicare has not screened) billing the program and receiving payment under the provider's enrollment.

We have the same concerns regarding Medicaid and CHIP. Each Medicaid or CHIP enrollment is specific to the enrolled provider and does not extend to any other party. To help protect against the improper use of a provider's enrollment by other persons or entities, we propose in new § 455.416(i) that the State must terminate enrollment if the provider knowingly sells or allows another individual or entity to use its enrollment to bill Medicaid or CHIP. We believe the language "use its enrollment to bill Medicaid or CHIP" is more appropriate than "use its billing number." The former is broader and can encompass any activity by which the other party bills Medicaid or CHIP via the provider's enrollment.

As with § 424.535(a)(7), there would be two exceptions to § 455.416(i). One would be for Medicaid and CHIP assignments of payment. Under § 447.10(g), payment for services provided by an individual practitioner may be made to—

- The employer of the practitioner, if the practitioner is required as a condition of employment to turn over the practitioner's fees to the employer;
- The facility in which the service is provided, if the practitioner has a contract under which the facility submits the claim; or
- A foundation, plan or similar organization operating an organized health care delivery system, if the practitioner has a contract under which the organization submits the claim.

We believe these provisions are akin to those under § 424.80, whereby the physician or practitioner permits a party with whom it has an employment or contractual relationship to bill for and collect payment for the services the individual provides. We thus conclude that an exception for payments permitted under § 447.10(g) is appropriate.

The second exception involves changes of ownership. Because State laws vary regarding: (1) what constitutes a change of ownership; (2) the consequences of such a change; and (3) the vetting and screening process for ownership changes, we propose that a State would not be required to terminate a provider under § 455.416(i) if State law permits another individual or entity to bill Medicaid or CHIP under the provider's enrollment in a change of ownership situation.

As with most of our other proposed grounds, the "best interests" exception would be included within § 455.416(i).

(10) Abusive Prescribing or Ordering of Services, Items, or Drugs (New §§ 455.416(j) and (k))

Existing §§ 424.535(a)(14) and (21) permit revocation of Medicare enrollment if we determine that the physician or eligible professional has a pattern or practice of--

- Prescribing Medicare-covered drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or fails to meet Medicare requirements. (§ 424.535(a)(14));

or

- Ordering, certifying, referring, or prescribing Medicare Part A or B services, items, or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements (§ 424.535(a)(21)).

We outlined our concerns about improper prescribing in our discussion of proposed § 455.416(h). The inappropriate ordering, certifying, or referring of services and items is equally concerning to us. If a physician or practitioner is improperly performing these activities, patient harm can ensue. For instance, a physician ordering tests that patients do not require could subject beneficiaries to dangerous and unnecessary procedures. Moreover, Medicaid and CHIP funds would be unnecessarily spent on these tests.

We believe States should take action against these individuals, not only to protect Medicaid and CHIP beneficiaries but also to safeguard the financial integrity of these programs. Accordingly, we propose to duplicate existing §§ 424.535(a)(14) and (21) in new § 455.416(j) and (k), though we note the following. First, all references in §§ 424.535(a)(14) and (21) to Medicare would be changed to "Medicaid or CHIP." Second, to avoid overlap, we would not include improper prescribing within new § 455.416(k) because we believe § 455.416(j) would adequately address this situation. Section 455.416(k) would be limited to services and items. Third, any references in §§ 424.535(a)(14) and (21) to eligible professionals would be changed in § 455.416(j) and (k) to physician or practitioner. Fourth, both paragraphs would include the "best interests" exception.

6. Additional Medicaid and CHIP Provider Enrollment Proposals

a. Database Reviews (§ 455.436)

Section 455.436 lists databases that States must review when (1) enrolling Medicaid and CHIP providers and (2) confirming their eligibility to remain enrolled. Section 455.436(b) lists the Excluded Parties List System (EPLS) as one of these databases. As this database is now named the System for Award Management (SAM), we propose in § 455.436(b) to replace

"Excluded Parties List System" with the former term. For the same reason, we propose to change "EPLS" in § 455.436(c) to "SAM."

b. Screening Levels (§ 455.450)

Section 424.518 discusses the different levels at which Medicare must screen initial applications, revalidation applications, and other application submissions. The levels are limited, moderate, and high. The categories are generally based on the assessed degree of program integrity risk each provider or supplier type poses; those types presenting the highest risk (for example, hospices) are in the "high" category.

Section 455.450 addresses the screening levels applicable to Medicaid enrollment. The first sentence in its opening paragraph states: "A State Medicaid agency must screen all initial applications, including applications for a new practice location, and any applications received in response to a re-enrollment or revalidation of enrollment request based on a categorical risk level of 'limited,' 'moderate,' or 'high." Consistent with section 1902(kk)(1) of the Act -- and as explained in the preamble to the aforementioned February 2, 2011, final rule -- for provider types that exist in both Medicare and Medicaid, the State must assign providers to the same or higher risk category applicable under Medicare in accordance with § 424.518. To codify this requirement in regulatory text, we propose to amend the opening paragraph of § 455.450 to add the following language between this paragraph's two existing sentences: "For provider types that also exist in Medicare, the State must assign such providers to the same or higher risk category applicable under Medicare in accordance with § 424.518."

c. Application Fees (§ 455.460)

Under § 455.460(a), the State must "collect the applicable application fee prior to executing a provider agreement from a prospective or reenrolling provider other than either of the following" persons or entities, which are listed in § 455.460(a)(1) and (2). We propose several changes to this section.

First, we propose to change the language "a prospective or re-enrolling provider" in

paragraph (a) to "a prospective, revalidating or re-enrolling provider" to clarify that revalidating institutional providers, consistent with section 1866(j)(2)(C) of the Act and current practice, must pay an application fee.

Second, we propose to remove the language "either of" in paragraph (a) because all parties listed in paragraph (2) are, as applicable, exempt from the fee.

Third, the purpose of the application fee is to cover the costs of screening provider applications under subpart E. As already noted, States must screen a provider's application at the same or a higher level than we use for that same provider type in Medicare and as prescribed in § 424.518. For instance, hospitals under § 424.518(a)(1) are subject to the "limited" risk category of screening; under § 455.450, States, too, typically screen hospital applications using the "limited" risk category procedures. However, States have the discretion under § 455.452 to screen an application using additional or more stringent methods than those required by subpart E. This helps States address local or statewide conditions involving provider types that may present a higher risk of fraud, waste or abuse and thus require stricter screening.

Section 455.460(a)(2)(ii) states that providers that have already paid the application fee to a Medicare contractor or to another State are exempt from paying a second fee to the State. This is because the State may rely on the screening results of the Medicare enrollment or the other State enrollment. Yet this becomes problematic when the State believes that a higher level of screening is warranted with respect to the provider's Medicaid or CHIP enrollment. Some States have expressed reluctance to screen at higher levels under § 455.452 because of the inability to collect an application fee under § 455.460(a)(2) to cover the costs of such screening. This has led to instances where the State has been unable, for financial reasons, to use enhanced screening methods when the State believed they were necessary. We are concerned that this has resulted in certain Medicaid providers having been insufficiently screened.

Section 455.460(a)(2)(ii) contains the language "(p)roviders that have paid the applicable application fee to (A) a Medicare contractor, or (B) (a)nother State". To address the previously

mentioned concerns, we propose the following:

- Redesignating paragraphs (a)(2)(ii), (a)(2)(ii)(A), and (a)(2)(ii)(B) as, respectively, paragraphs (a)(2)(ii)(A), (a)(2)(ii)(A)(*1*), and (a)(2)(ii)(A)(*2*);
- Changing "providers that have paid the applicable application fee" to "Subject to paragraph (2)(ii)(B), providers that have paid the applicable fee…"; and
- Establishing a revised paragraph (ii)(B) that reads: "Paragraphs (2)(ii)(A)(*1*) and (*2*) do not apply if the State is screening the provider at a higher level under § 455.450 than the Medicare contractor or other State to which the provider paid the fee. In this situation, the State may collect a fee from the provider that represents the cost of this additional screening above and beyond the level of screening the Medicare contractor or State performed under §455.450. However, the State shall document the reason(s) for the enhanced screening."

To illustrate how revised paragraph (ii)(B) would work, assume State A screened a fee-paying enrolling provider at the "moderate" level. Said provider now submits an enrollment application to State B, which believes the provider should be screened at the "high" level. State B's "high" level screening typically costs Y dollars and its "moderate" level screening X dollars. State B could require the provider to pay the difference between Y and X to reflect the additional screening activities; States would have the discretion to determine the cost of this additional screening. We believe that payment of the difference between the two screening levels' costs would be fairer to the provider than requiring payment of another full application fee. We also note that revised paragraph (ii)(B) would only apply to providers that have paid the applicable fee to the Medicare contractor or other State. Providers that, for example, received a hardship exception from paying the fee to the Medicare contractor or other State would not have the pay the costs of the additional screening.

In summary, we believe that revised paragraph (ii)(B) would assist the States in their efforts to appropriately screen Medicaid and CHIP providers by removing the disincentive for elevated screening. This would, in turn, enhance Medicaid and CHIP program integrity. To

ensure that States have sufficient grounds for requiring a fee under (ii)(B), though, we believe that States should document the need for the enhanced screening.

d. Monthly Reporting of Denials and Terminations to CMS

Consistent with sections 1902(kk)(8) and 1902(ll) of the Act as well as § 455.417, CMS operates a "termination database." This database contains information on certain Medicaid and CHIP terminations and Medicare revocations. Per Sections 1902(kk)(8) and 1902(a)(41) of the Act, the State must report to the Secretary all its provider terminations under Medicaid and CHIP that are "for cause" (as defined in § 455.101) within 30 days after the effective date of the termination, which is the later of the effective date specified in the termination notice or the date appeal rights have been exhausted. Although CMS reviews these terminations in the database, the latter does not capture: (1) denials of Medicaid or CHIP enrollment; or (2) situations where the State chose not to deny or terminate enrollment based on a best interests determination. We believe that despite the termination database's usefulness, the lack of certain information about the State's denial and termination decisions hinders our ability to detect and address vulnerabilities in the Medicaid and CHIP provider enrollment processes.

To address this gap, we propose in new § 455.418 that each State must submit to CMS on a monthly basis – and in a format required by CMS -- the legal business and doing business names, address, TIN, and NPI of each provider (Medicaid or CHIP) whose enrollment, within the applicable monthly period, the State--

- Denied or terminated under § 455.416. This must include--

++ The regulatory basis for the denial or termination.

++ The facts of the case and an explanation of how the State reached its decision.

- Was required to deny or terminate under § 455.416 but declined to do so based on a best interests finding. This must include--

++ The regulatory basis for the prospective denial or termination; and

++ The facts of the case, an explanation of how the State reached its decision, and

reasons for the State's best interests determination.

CMS would issue guidance to States on the required format should this provision be finalized.

In new paragraph (b), we would remind stakeholders that the requirements of § 455.418 would be in addition to, and not in lieu of, the reporting requirement under sections 1902(kk)(8) and 1902(a)(41). That said, they would only apply to denials or terminations pursuant to § 455.416 and not those under separate State authority that might meet the definition of "for cause" for purposes of those provisions.

H. Medicare Advantage Original Medicare Provider Enrollment Requirements

1. Background

a. General Overview

The Balanced Budget Act of 1997 (BBA) established a new Part C of the Medicare program, known as Medicare+Choice (M+C), effective January 1999. As part of the M+C program, the BBA authorized CMS to contract with public or private organizations to offer a variety of health plan options for enrollees, including both traditional managed care plans (such as those offered by HMOs, as defined in section 1876 of the Act) and new options not previously authorized. The M+C program was renamed the Medicare Advantage (MA) program under Title II of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173), which was enacted on December 8, 2003. The MMA changed how benefits are established and payments are made; under the MMA, enrollees were able to choose from additional plan options. Also, Title I of the MMA established the Medicare prescription drug benefit (Part D) program and amended the MA program to allow most MA plans to offer prescription drug coverage.

All Medicare health plans (but not Program of All-inclusive Care for the Elderly (PACE) organizations) that specify networks of providers from whom enrollees may obtain services must develop a network of qualified providers that meets CMS network adequacy standards as

detailed in § 422.116. CMS reviews MA organizations' network of contracted providers on a routine basis, unless there is a triggering event that would require an expedited formal network review, such as a significant provider termination.

b. The 2016 and 2018 Part C Provider Enrollment Regulations

In November 2016, CMS issued a final rule (81 FR 80170) containing various requirements related to provider enrollment,[157] including the addition of § 422.222. This section required providers and suppliers that furnish health care items or services to a Medicare enrollee who receives their Medicare benefit through an MA organization to be enrolled in Original Medicare (also known as Medicare fee-for-service (FFS)) in an approved status no later than January 1, 2019. (The term "MA organization" refers to both organizations offering stand-alone MA plans and MA plans that provide drug coverage, otherwise known as MA-PD plans.)

The general purpose of this requirement was to ensure that MA providers and suppliers (hereafter collectively "providers" unless otherwise noted) were fully screened via the provider enrollment process used for Original Medicare Part A and Part B providers. As previously noted in this proposed rule, Original Medicare Part A and Part B provider enrollment screening is comprehensive. It involves the collection and verification of critical data such as the provider's identity, address, licensure and other qualifications, practice location, owners, managing employees, and adverse legal history. Depending on the provider type, it can also include site visits and fingerprint-based criminal background checks. The thoroughness of this process was invaluable in protecting the Medicare program from fraud, waste, and abuse as well as Medicare beneficiaries from unqualified providers. Given that many providers at the time underwent less robust screening by their prospective MA organizations before becoming MA providers, we

[157] "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements"

believed that our requirement would help safeguard the MA program and its beneficiaries (hereafter occasionally "enrollees").

We began outreach efforts shortly after the November 2016, final rule's publication. We communicated with provider associations and MA organizations regarding, among other things, the purpose of the enrollment process, the rationale for the new enrollment requirement, and the mechanisms of completing and submitting an enrollment application. While the vast majority of MA providers and suppliers were already enrolled in Original Medicare and thus met the new MA provider enrollment requirement, over 100,000 were not. This led the MA community to raise concerns about the potential burden of this requirement, especially since MA providers also must undergo credentialing by their respective MA organizations.

In response to these concerns, we issued a final rule in April 2018 (83 FR 16440) that eliminated the MA provider enrollment requirement at § 422.222.[158] In its place, we established in § 422.222 a "preclusion list." The preclusion list for contracted and non-contracted individuals and entities is a list of providers that are precluded from receiving payment for MA services and items they furnish. Per the definition of "preclusion list" in § 422.2, there are three ways individuals and entities can be added to the list:

- The individual or entity is currently revoked from Medicare, is currently under a reenrollment bar, and CMS has determined that the underlying conduct that led to the revocation is detrimental to the best interests of the Medicare program.

- The individual or entity has engaged in behavior for which CMS could have revoked the individual or entity to the extent applicable if they had been enrolled in Medicare, and CMS determines that the underlying conduct that would have led to the revocation is detrimental to the best interests of the Medicare program.

[158] "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program"

- Regardless of whether they are or were enrolled in Medicare, the individual or entity has been convicted of a felony under Federal or State law within the previous 10 years that CMS deems detrimental to the best interests of the Medicare program. (We proposed in the CY 2027 HH PPS proposed rule (91 FR 41216) to expand this to include felony convictions against the individual or entity or an owner, managing employee, managing organization, director, or officer (as those terms are defined in § 424.502) thereof.))

For purposes of burden reduction, the April 2018 final rule also replaced the requirement that prescribers of Medicare Part D drugs be enrolled in Original Medicare with a preclusion list for Part D prescribers, addressed in § 423.120(c)(6).

c. Preclusion List and Part C Program Integrity Issues

The preclusion list for MA providers has been in effect since 2019. For several reasons, though, we are reevaluating its effectiveness in stemming MA fraud, waste, and abuse in comparison to the proven program integrity safeguards of our existing Medicare provider enrollment process.

First, while many MA organizations require providers to be enrolled in Original Medicare as a condition of contracting,[159] well over 100,000 in-network providers remain unenrolled. In certain cases, a particular MA organization's credentialing process may not be as comprehensive as Original Medicare enrollment screening. The latter, for example, contains the following verification mechanisms that do not necessarily exist in the MA organizations' internal process:

- Reviewing the provider and its owners and managing employees against the System for Award Management, which lists debarment actions taken by various Federal agencies.

- Reviewing the provider's adverse legal history, such as criminal convictions, health care program revocations and suspensions, and adverse State licensure actions.

[159] Recent CMS data indicates that approximately 90 percent of in-network MA providers—over one million—are enrolled, meaning that they are already subject to the strict screening of Original Medicare enrollment.

- Fingerprint-based criminal background checks for 5 percent or greater owners of provider types designated as high-risk under § 424.518.
- Reviewing the Medicaid Termination Database under § 455.417 to ascertain whether the provider is terminated under Medicaid or CHIP.
- Monthly monitoring to ensure the provider's continued compliance with licensure and other enrollment requirements.
- Verifying the validity of the provider's practice location.
- Requiring the provider to revalidate its Medicare enrollment information (including upon a CMS request) by submitting a complete Medicare enrollment application.

Most disconcerting of all is that out-of-network providers that bill MA may not be credentialed by any MA organization, meaning they receive little, if any, screening. This leaves the MA program vulnerable to fraud, waste, and abuse.

As noted, Original Medicare enrollment is the front line of Medicare program integrity. It enables us to detect and stop non-compliant and potentially fraudulent parties from billing MA at the start, rather than after they begin doing so. Without this important vetting, we have limited means of preventing unqualified providers from entering MA and possibly harming the Trust Funds and MA enrollees.

Second, and in this same vein, we see the preclusion list as more of a reactive program integrity measure than a proactive one. For MA providers that are not enrolled in Original Medicare, we sometimes do not learn that the provider has engaged in fraudulent or other improper conduct until the MA organization itself discovers this and informs us. Only then can we begin the process of placing the provider on the preclusion list. By the time all this occurs, many months may have passed, hundreds of thousands of MA organization dollars may have been paid to the provider, and considerable harm to MA enrollees may have taken place. In other words, in such cases CMS effectively must wait: (1) for the inappropriate activity to happen; (2) for the inappropriate activity to be discovered by the MA organization (potentially months after

it occurred); and (3) to be notified by the MA organization before CMS can commence action against the provider. This directly contradicts our stated objective of moving away from the "pay-and-chase" program integrity model and towards the far better approach of halting fraud before it begins.

Third, pursuant to § 422.222(a)(3), the following timing conditions apply to the addition of an individual or entity (other than an OIG-excluded party) to the MA preclusion list:

- If the individual or entity (hereafter occasionally and collectively referenced as "party") does not file a reconsideration request under § 498.5(n)(1), the party is added to the preclusion list upon the expiration of the 60-day period in which the party may request a reconsideration; or
- If the party files such a reconsideration request, they are added to the list effective the date on which CMS, if applicable, denies reconsideration. OIG-excluded parties are added to the preclusion list effective on the date of the exclusion.

This means that even though CMS believes an individual or entity has, for instance, engaged in fraud, beneficiary harm, or felonious conduct, CMS cannot take any action against that individual or entity via the preclusion list for at least 60 days -- and if said party files a reconsideration request, CMS action could take considerably longer. Yet with Original Medicare provider enrollment, CMS can immediately revoke the provider's enrollment without having to wait for the expiration of any appeals process, thus providing further protection for Medicare funds and beneficiaries. In addition, many of the Medicare enrollment revocation reasons in § 424.535(a) are retroactive, meaning the revocation effective date -- in general and with variations -- essentially goes back to the date the provider's non-compliance with Original Medicare enrollment requirements began. This enables CMS to recoup monies paid to the provider while they were non-compliant.[160] (We also proposed in the CY 2027 HH PPS

[160] We are also proposing in the CY 2027 HH PPS proposed rule to make the remainder of our Medicare revocation reasons retroactive.

proposed rule to make the remainder of our Medicare revocation reasons retroactive.) Accordingly, requiring providers that bill MA to enroll in Original Medicare , and hence be subject to retroactive revocations in cases of non-compliance, would likely go further in the MA realm in safeguarding taxpayer monies and protecting MA enrollees than the preclusion list.

Too, we have seen a growing trend of providers foregoing Original Medicare enrollment and instead billing MA organizations as out-of-network providers. This only enhances the need for the comprehensive, up-front screening process that Medicare provider enrollment furnishes.

We recognize that proposing to require MA providers (both in-network and out-of-network) to be Original Medicare-enrolled would, if finalized, be a change in position from our prior decision to have the preclusion list replace the enrollment requirement. We also appreciate providers' likely concerns about the potential burden of having to enroll. Yet we note two things.

One is that several of the aforementioned issues concerning the preclusion list–such as the time it can take for CMS to learn of an MA provider's misconduct–were not as apparent as they are now. In fact, in September 2026, as part of the White House Anti-Fraud Task Force's ongoing efforts to crush fraud in the healthcare system and protect taxpayer dollars, CMS identified and barred via the preclusion list 11 DME companies with more than $3.4 billion in suspected fraudulent billing practices in 2025 and 2026 from receiving future Part C and Part D payments. These 11 DMEPOS suppliers: (1) had submitted no claims prior to 2025; (2) used improper billing practices for their claims; (3) had billed for medical equipment to beneficiaries already deceased; and (4) supplied equipment to beneficiaries who never requested or received it. Four of the suppliers had already been revoked from Original Medicare and began billing MA organizations instead.[161] This is one illustration of how the preclusion list is a useful tool once potential fraud has been identified but can fall short when fraud is being targeted at MA plans

161 https://www.cms.gov/newsroom/press-releases/cms-cracks-down-massive-3-4-billion-medical-equipment-supplier-fraud-scheme

instead of Original Medicare, especially when those targeting MA are out-of-network providers. MA credentialing by itself is often not as rigorous as the Medicare provider enrollment process (as previously shown in the bulleted list of verification activities that some MA plans do not undertake), and the lack of screening for out-of-network providers is an extremely serious vulnerability; the increasing number of out-of-network providers greatly heightens this risk to the MA program. Circumstances have changed, and our obligation to protect the Trust Funds requires us to be flexible in our program integrity activities and to modify them as warranted.

As discussed in more detail in this proposed rule's ICR section, roughly 150,000 MA providers (many being out-of-network) would have to enroll in Medicare. While we again acknowledge this burden, we stress that the payment of MA dollars to fraudulent or otherwise unqualified providers burdens all Americans, including legitimate MA providers. Indeed, a single fraud scheme involving several MA providers that had not been adequately vetted before they began providing MA services – when strict enrollment screening might have kept them out of the MA program – could alone result in tens of millions of dollars in lost taxpayer monies. The point is that the cost burden of MA provider enrollment would, we believe, ultimately be far less than the savings to bona fide MA providers and all other Americans from MA fraud and abuse prevention.

For all these reasons, we propose to require that all providers that bill MA be enrolled in Original Medicare. This proposal is aligned with Department of Health and Human Services Office of Inspector General's September 2026 report on CMS actions to prevent durable medical equipment fraud in MA.[162] The proposed regulatory changes that follow largely mirror those we finalized in the previously mentioned November 2016 final rule. An important modification, though, would be our proposal to expand the enrollment requirement to include out-of-network MA providers, which were not required to enroll under the November 2016 final rule. CMS is

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162 Medicare Advantage Organizations and CMS Can Do More To Prevent Durable Medical Equipment Fraud in Medicare Advantage

proposing to include out-of-network MA providers in this requirement to address the earlier noted program integrity threats associated with these parties.

To give unenrolled MA providers adequate time to enroll in Original Medicare and MA organizations adequate time to operationalize this requirement, our changes, if finalized, would not become applicable until January 1, 2030. This timeframe is somewhat akin to that which we finalized in November 2016 final rule, which was the first day of the next plan year that begins 2 years after the date of publication of that final rule. Until this January 1, 2030, applicability date, the MA preclusion list requirements would remain in effect.

We are not at this time proposing that Part D prescribers be required to enroll in Original Medicare in lieu of the preclusion list. We may consider doing so in future rulemaking.

d. Statutory Authority

The following are the principal legal authorities for our proposed MA enrollment requirement:

- Section 1856(b) of the Act, which provides that the Secretary shall establish by regulation other standards for Medicare+Choice organizations and plans consistent with, and to carry out, Part C.
- Section 1857(e)(1), which gives CMS the authority to implement additional MA contract terms and conditions not inconsistent with Part C as the Secretary may find necessary and appropriate.
- Sections 1102 and 1871 of the Act, which provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.
- Section 1866(j) of the Act, which provides specific authority with respect to the enrollment process for providers and suppliers in the Medicare program.

2. Specific Regulatory Changes

We propose the following regulatory revisions:

a. Proposed Provisions "Preclusion List" Definition (§ 422.2)

In light of the foregoing, we propose the following regulatory revisions. Note that a number of these reflect that our existing MA preclusion list provisions would remain in effect up to December 31, 2029. Also, the MA definition of "providers" in § 422.2 includes individuals and entities that would be considered either providers or suppliers in original Medicare; we will hence use the term "provider" in our proposed regulatory provisions except as other noted.

In the opening clause of this definition, we propose to replace the language that reads "means a CMS compiled list" with "means, before January 1, 2030, and with respect to this part, a CMS compiled list". This would clarify that the definition only applies to Part 422 through December 31, 2029, after which the enrollment requirement would replace the preclusion list for MA. [163]

b. Documented Process (§ 422.204(c))

Section 422.204(c) states that an MA organization must follow a documented process that ensures compliance with the preclusion list provisions in § 422.222. We propose to redesignate this paragraph as new § 422.204(c)(1) and to insert "Before January 1, 2030," at the beginning of the paragraph. This would elucidate that § 422.204(c)(1) only applies through December 31, 2029.

New § 422.204(c)(2) would state that beginning January 1, 2030, an MA organization must follow a documented process that ensures compliance with the provider enrollment provisions in § 422.223 (addressed shortly). We believe this would help facilitate MA organizations' verification of the provider's Original Medicare enrollment status.

c. Various Preclusion List Requirements (§ 422.222)

Section 422.222 outlines a number of provisions and requirements regarding the preclusion list for contracted and non-contracted entities and individuals. We propose to add the

[163] In the CY 2027 HH PPS proposed rule, we proposed to expand the preclusion list's breadth to include felony convictions against the provider/prescriber's owner, managing employee, managing organization, corporate director, or corporate officer.

following language immediately prior to subsection (a): "The provisions of this section apply before January 1, 2030."

d. New Enrollment Section (§ 422.223)

To address some of our new enrollment requirements (including outlining the parties to which they apply), we propose to establish a new § 422.223. We believe that promulgating a new, separate section would be clearer for stakeholders than attempting to incorporate our new provider enrollment provisions within § 422.222. Section 422.223's opening paragraph would state that beginning January 1, 2030, providers that are types of individuals or entities that can enroll in Original Medicare (in accordance with section 1861 of the Act) must be so enrolled in Original Medicare in an approved status to receive payment from an MA organization for health care items or services provided to a Medicare enrollee who receives their Medicare benefit through the MA organization. (For purposes of this requirement, "approved status" means the provider is neither revoked from Medicare under § 424.535 nor deactivated under § 424.540.) As outlined in new § 422.223(a)(1) through (6), this would include the following providers and suppliers:

- In-network and out-of-network MA providers.
- First-tier, downstream, and related entities (FDR), as these are defined at § 422.2.[164]
- Providers in Health Maintenance Organizations (HMOs) or Competitive Medical Plans that contract with CMS under section 1876 of the Act.
- Providers participating in demonstration programs or in pilot programs.[165]
- Locum tenens providers.
- Incident-to providers.

[164] Current rules allow MA organizations to contract with different entities to provide services to beneficiaries. These contracted entities are referred to as first-tier, downstream, and related entities or FDRs, as defined in § 422.500.

[165] Demonstrations and pilot programs, also called research studies, are special projects that test improvements in Medicare coverage, payment, and quality of care. They usually operate only for a limited time for a specific group of people and/or are offered only in specific areas.

With the exception of out-of-network MA providers, these six provider categories were included within our MA enrollment requirement in the November 2016 final rule. Both then and now, we believe that patients of these providers should benefit from the protections afforded by the very thorough and comprehensive provider screening processes in 42 CFR Part 424, subpart P. Existing § 422.222(b) states that an MA organization that does not comply with § 422.222(a) may be subject to sanctions under § 422.750 and termination under § 422.510. We propose a similar provision in new § 422.223(b) regarding our enrollment requirement. Considering the serious risks to the Medicare program and its beneficiaries from fraudulent or otherwise unqualified providers, it is necessary to stress to MA organizations the consequences of non-adherence to § 422.223(a).

e. Excluded, Revoked, and Precluded Providers

Section 422.224(a) states, in part, that an MA organization may not pay for items or services furnished to a Medicare enrollee by an individual or entity that is OIG excluded or on the preclusion list. Section 422.224(b) states, also in part, that if the MA organization receives a request for payment by, or on behalf of, such an excluded or precluded individual or entity, the MA organization must notify the enrollee and the excluded or precluded party that payment will not be made; the paragraph adds that payment cannot be made to, or on behalf of, an excluded or precluded person or entity. We propose to re-designate these paragraphs as new § 422.224(a)(1) and (a)(2). Consistent with our aforementioned revisions, we would also add the following after the paragraph (a) designation: "Before January 1, 2030". This will clarify these paragraphs' applicability. In new paragraph (b), we would largely duplicate proposed new §§ 422.224(a)(1) and (a)(2) but with two modifications. First, the requirements would apply beginning January 1, 2030. Second, we would leave precluded parties within the scope of these sections but change it to refer to Part D prescribers that are on the preclusion list as defined in § 423.100 and as described in § 423.120(c)(6). We believe that the program integrity risk that all parties on the preclusion list pose – be they MA or Part D – warrants the inclusion of the latter within §

422.224(b). (The existing reference in § 422.224 to precluded MA providers, though, would not be retained in § 422.224(b) because the preclusion list will not be applicable to MA providers beginning January 1, 2030.)

We also would include the language "revoked from Medicare" in revised § 422.224(b). As we stated in the November 2016 final rule and have reiterated in others since then, revoked providers and suppliers pose a significant risk to Medicare beneficiaries and the Trust Funds and should not receive Federal dollars. This is why we originally included revoked providers within the scope of § 422.224(a) in the November 2016 final rule and propose to do so in revised § 422.224(b). For this same reason, we are not proposing a "first-time allowance" (FTA) – similar to what we did in the April 2018 MA preclusion list final rule with respect to precluded providers -- in which payment could be made the first time the revoked provider submits a claim but not thereafter. The objective behind any FTA would be to prevent beneficiaries from being liable for payment when the first claim is denied due to the provider's revocation. The beneficiary is notified that while payment will be made in this instance, future payments to the provider will not be; this means the beneficiary should seek a different provider to ensure that the beneficiary's services are covered. However, we explained in the November 2016, final rule that beneficiaries would already be protected in these situations per 42 CFR 1001.1901(b) and § 424.555(b), which prevent OIG-excluded individuals and entities (as well as revoked, deactivated, and denied providers) from recouping payment from beneficiaries. There is accordingly no need for an FTA.

f. HMOs and Competitive Medical Plans

Sections 417.478(e)(1) and (2) state, in part, that the prohibitions, procedures, and requirements relating to payment to individuals and entities on the preclusion list apply to HMO and Competitive Medical Plans that contract with CMS under section 1876 of the Act. We propose to redesignate these paragraphs as new § 417.478(e)(1)(i) and (ii) with the "Before January 1, 2030" caveat. Proposed new § 417.478(e)(2)(i) and (ii), meanwhile, would mostly

duplicate new § 417.478(e)(1)(i) and (ii), though with (1) applicability beginning on January 1, 2030, and (2) all MA preclusion list references changed to the enrollment (and the non-payment to an unenrolled, excluded, revoked, or § 423.120(c)(6) precluded provider) requirements in §§ 422.223 and 422.224. This would make clear that these provisions, as noted, apply to HMOs and Competitive Medical Plans that contract with CMS under section 1876 of the Act.

g. Additional Regulatory Revisions to Accommodate Our Proposed Enrollment Requirements

- Under §§ 422.510(a)(4)(xiii) and 422.752(a)(13), CMS may sanction or terminate an MA organization for failure to comply with the preclusion list requirements at § 422.222 or § 422.224, such as by making payment to parties on the preclusion list. We propose to re-designate these provisions as new §§ 422.510(a)(4)(xiii)(A) and 422.752(a)(13)(i) with an applicability date before January 1, 2030. In new §§ 422.510(a)(4)(xiii)(B) and 422.752(a)(13)(ii), which would apply beginning January 1, 2030, the former would reference non-compliance with the requirements of §§ 422.223 and 422.224(b) instead of compliance with the preclusion list requirements. For § 422.752(a)(13)(ii), we propose to reference the MA organization's failure to comply with §§ 422.223 and 422.224(b), which require the MA organization not to make payment to providers that are OIG-excluded, revoked from Medicare, precluded under § 423.120(c)(6), or that can enroll in Medicare under section 1861 of the Act but are not so enrolled in an approved status.

- Sections 422.501(c)(1)(iv) and (2) state that in completing an application to become an MA organization under § 422.510, an entity must, among other things, furnish documentation that "payment for health care services or items is not being and will not be made to individuals and entities included on the preclusion list, defined in § 422.2." We would redesignate these paragraphs as new §§ 422.501(c)(1)(iv)(A) and (2)(i) with a "before January 1, 2030" applicability date. In new §§ 422.501(c)(1)(iv)(B) and (2)(ii), which would apply beginning January 1, 2030, we proposed to reference the need for documentation demonstrating and verifying that payment for health care services and items is not being and will not be made to

providers and suppliers that can enroll in Medicare in accordance with section 1861 of the Act but that are not enrolled in an approved status. These changes would align with our proposed enrollment requirement, and the addition of "demonstrating and verifying" will help clarify the scope of the required documentation.

- Sections 422.504(a)(6), (g)(1)(iv), (g)(1)(v)(B), and (i)(2)(v) describe several of the required terms of a CMS contract with an MA organization with respect to the preclusion list. Specifically, the MA organization must:

++ Agree under (a)(6) to comply with the preclusion list requirements in §§ 422.222 and 422.224.

++ Ensure under (g)(1)(iv) that the enrollee does not have any financial liability for services, items, or drugs furnished, ordered, or prescribed to the enrollee by an MA contracted individual or entity on the preclusion list.

++ Ensure under (g)(1)(v) that the plan's provider agreement contains the provisions in paragraphs (g)(1)(v)(A) and (B) regarding provider payment and financial liability after the expiration of the 60-day period specified in § 422.222.

++ Agree under § 422.504(i)(2)(v) to require all FDR entities to ensure that payments are not made to individuals and entities on the preclusion list.

We propose the following revisions to these paragraphs. First, we would clarify in paragraph (a)(6) that the preclusion references therein only apply before January 1, 2030. Second, new paragraph (a)(22) would require compliance with the requirements of §§ 422.223 and 422.224(b) beginning January 1, 2030. Third, we would split paragraph (g)(1)(iv) into new paragraphs (g)(1)(iv)(A) and (B). Paragraph (g)(1)(iv)(A) would consist of existing paragraph (g)(1)(iv) with the "Before January 1, 2030" caveat. Paragraph (g)(1)(iv)(B) would include the "Beginning January 1, 2030" language and replace references to the preclusion list with references to unenrolled MA providers. Fourth, we would add "Before January 1, 2030" at the beginning of paragraph (g)(1)(v). Lastly, we would redesignate paragraph (i)(2)(v) as new

paragraph (i)(2)(v)(A) with the "before January 1, 2030" qualifier. In new paragraph (i)(2)(v)(B) we would include the language "providers that are eligible to enroll in Medicare under section 1861 of the Act but that are not enrolled in Medicare in an approved status", with an effective date of January 1, 2030.

- Section 422.2267(e) lists certain communications materials that must be provided to prospective or current MA plan enrollees. Paragraph (e)(15) references an "excluded provider notice" whereby plans must notify enrollees when a provider they visit or consult is OIG-excluded or is on the preclusion list. We propose to redesignate paragraph (e)(15) as new paragraph (e)(15)(i) with the "before January 1, 2030" caveat. In new paragraph (e)(15)(ii) - applicable beginning January 1, 2030, and consistent with our other proposed changes – we would include unenrolled, excluded, revoked, and § 423.120(c)(6) precluded providers within this notification requirement.

- Section 417.484(b)(3) pertains to "related entities", which is defined in paragraph (a) as any entity that is related to the HMO or Comprehensive Medical Plan by common ownership or control and meets the requirements of paragraphs (a)(1) through (3). Section (b)(3) states that the contract must provide that the HMO or Comprehensive Medical Plan agrees to require all related entities to agree that payments must not be made to parties on the preclusion list as defined in § 422.2. We propose to redesignate this paragraph as new paragraph (b)(3)(i) with the "before January 1, 2030" qualifier. New paragraph (b)(3)(ii) would apply beginning January 1, 2030, regarding providers that are eligible to enroll in Medicare in accordance with section 1861 of the Act but are not enrolled in Medicare in an approved status.

- Part 498 of Title 42 addresses certain appeal rights. Section 498.3(b)(20) includes a party's placement on the preclusion list (as defined in §§ 422.2 or 423.100) as an initial determination. Section 498.5(n)(1)(i) outlines appeal rights for these parties. We propose to divide § 498.3(b)(20) into subparagraphs (i) and (ii). Sub-paragraph (i) will be limited to parties on the preclusion list as defined in § 423.100 – that is, Part D prescribers; sub-paragraph (ii) will

apply to precluded individuals and entities per § 422.2 before January 1, 2030. We propose the same for paragraph § 498.5(n)(1)(i), which would be split into paragraphs (n)(1)(i)(A) and (B) with the former applying to Part D precluded parties, and the latter to MA parties before January 1, 2030.

3. Solicitation of Comments

We recognize that there are certain circumstances in which an MA organization is obligated to pay a provider regardless of that party's contract status with the plan or for a benefit that is not covered under Original Medicare. The following are illustrative.

First, under § 422.113, an MA organization must cover and pay for emergency and urgently needed services, regardless of whether the provider has a contractual relationship with the plan.

Second, MA organizations are required to pay for out-of-network services in certain circumstances, such as:

- When an MA organization's provider network is insufficient to furnish a covered service (such that an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs), the organization must arrange for, and pay for, that service from an out-of-network provider; and
- When the enrollee is in a PPO plan, which is required to reimburse for covered services obtained out-of-network.

Third, supplemental benefits that MA organizations may offer under section 1852(a)(3) of the Act are, by definition, items and services not covered under Original Medicare Parts A and B; providers furnishing these benefits may not have a basis to maintain Medicare FFS enrollment.

We also recognize that while we believe our proposed provisions are very much necessary, stakeholders – as after the November 2016 final rule was issued – may be concerned about certain aspects of these requirements. These could involve, for example, the potential

burden, impact on beneficiary financial liability and access to care, and whether certain provisions might or should be inapplicable to certain situations. We wish to be as responsive as possible to such concerns within the parameters of our program integrity objectives. Accordingly, we welcome and encourage public comments on our proposed provisions, especially concerning the following issues:

- Whether § 422.222 should include an exception for providers furnishing: (1) emergency or urgently needed services under § 422.113; (2) services furnished when the MA organization is required under § 422.112(a)(1)(iii) and § 422.4(a)(1)(v)(B) to cover or arrange for out-of-network coverage; and (3) supplemental benefits not covered under Original Medicare. In Moreover, we request feedback on how any such exception should be structured to avoid creating a loophole that could be exploited to circumvent the enrollment requirement's program integrity purpose.

- Whether the payment safeguards proposed at § 422.224 should still apply to these three aforementioned illustrations.

- Whether there should be any other exceptions to our enrollment requirements and, if so--

  ++ The reason(s) for the exception(s);

  ++ The situations in which they should or should not apply; and

  ++ The sub-category or sub-categories of MA providers to which they should apply.

- Whether any of our proposed six categories of applicability in proposed § 422.223 should or should not be included therein – as well as any clarification needed regarding the scopes and meanings of said categories (for example, the scope of the locum tenens and incident-to categories). Conversely, we ask stakeholders whether any provider types not listed in § 422.223 – such as PACE providers – should be subject to our enrollment requirements.

We ask stakeholders to be as specific and detailed as possible in describing their recommended exemptions, requested clarifications, etc. Suggested regulatory text – and its

location within the CFR -- would be appreciated, as well as recommended limitations or clarifications on the scope of any of the proposed categories.

- The network adequacy requirements in § 422.116, including whether our provider enrollment proposals would impact the ability of MA organizations to meet network adequacy standards, especially in Rural or Counties with Extreme Access Considerations (CEAC) areas.

- The extent of any access to care issues that stakeholders believe might arise, where and why they may occur, and recommendations on how they could be alleviated within the context of our proposal, including any recommended regulatory text.

- Suggestions regarding the limitation of beneficiary financial liability for services performed by unenrolled providers -- for instance:

++ Whether enrollee liability should be capped at normal in-network cost-sharing whenever the plan is barred from paying a provider under § 422.224 for services the enrollee was otherwise permitted to receive under §§ 422.4, 422.112, or 422.113.

++ Whether and how MA organizations should ensure the MA enrollee is not liable for care provided by unenrolled providers.

++ Additional situations where stakeholders believe that beneficiary liability should be restricted, including suggested regulatory text and their locations with the CFR.

- Requested CMS educational activities concerning our proposed requirements (such as those we performed following the November 2016 final rule)

- Costs that MA organizations might incur in implementing our provisions.

- Any other CFR sections that stakeholders believe should be added, revised, or updated to accommodate our proposed MA enrollment requirements.

VI. Marketplace

In recent years, there has been a substantial increase in complaints from consumers who reported that they were unaware they had been enrolled in Exchange coverage or that their Exchange plan had been switched without their consent by an agent, broker, or web-broker. From 2023 through 2025, CMS received over 624,000 consumer complaints attesting to unauthorized Exchange enrollments[166] or unauthorized plan switching[167] by agents, brokers, or web-brokers and confirmed by issuer and CMS review; 300,000 of the 624,000 were received in 2025 alone.[168] These improper enrollments constitute abusive conduct that costs Federal taxpayers billions of dollars. For example, the HHS Agency Financial Report for Fiscal Year 2025 estimates improper payments of Premium Tax Credits totaled about $1.13 billion.[169]

Abusive conduct by agents, brokers, and web-brokers, such as unauthorized enrollments and unauthorized plan switching, can cause significant medical or financial harm to consumers. For example, enrolling consumers in Exchange plans or changing a consumer's Exchange plan without their consent can cause financial harm, such as unexpected tax liabilities and higher copayments and deductibles. It can also cause physical harm by interrupting their access to medical care when an unauthorized new plan does not cover their medications or include their established providers in-network.[170] CMS has identified an ongoing pattern of unauthorized enrollment, unauthorized plan switching, and other fraudulent, unauthorized, or noncompliant enrollment activity involving a subset of agents, brokers, and web-brokers participating in the

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[166] An unauthorized enrollment is when an enrollment occurred in Exchange coverage without consumer consent.
[167] An unauthorized plan switch is when an Exchange plan was changed without consumer consent.
[168] *See* U.S. Government Accountability Office. (2025 December) *Patient Protection and Affordable Care Act: Preliminary Results from Ongoing Review Suggest Fraud Risks in the Advance Premium Tax Credit Persist*, (Publication No. GAO-26-108742). *https://www.gao.gov/products/gao-26-108742* (explaining, "Based on our preliminary analyses, we identified at least 30,000 applications in plan year 2023 and at least 160,000 applications in plan year 2024 that had likely unauthorized changes."). *See also* U.S. Government Accountability Office. (2026 July) *Health Insurance Marketplaces: CMS Needs Stronger Controls to Prevent Unauthorized Actions by Agents and Brokers*, (Publication No. GAO-26-108297). *https://www.gao.gov/products/gao-26-108297.*
[169] U.S. Department of Health and Human Services. (2025). *FY 2025 agency financial report (p. 157)*. https://www.hhs.gov/sites/default/files/fy-2025-hhs-agency-financial-report.pdf.
[170] U.S. Government Accountability Office. (2025). *Patient Protection and Affordable Care Act: Preliminary results from ongoing review suggest fraud risks in the Advance Premium Tax Credit persist* (Publication No. GAO-26-108742) (Pg. 2). *https://www.gao.gov/products/gao-26-108742*.

Federally-facilitated Exchange (FFEs) and State-based Exchanges on the Federal platform (SBE-FPs).[171] While CMS has taken a number of steps to address this conduct, the conduct has persisted. For example, on August 31, 2026, CMS canceled approximately 315,000 enrollments covering over 760,000 consumers after following its standard issuer investigation process to confirm that these enrollments were unauthorized. Similarly, CMS is also holding agents, brokers, and web-brokers accountable for violating Marketplace standards. Since January 2026, CMS has issued termination notices to more than 200 non-compliant agents and brokers. Furthermore, in the summer of 2026, CMS issued 569 notices of intent to terminate to agents and brokers who submitted 2026 applications without key-identifying applicant information, such as Social Security Numbers (SSN).

When an agent, broker, or web-broker enrolls someone in a Marketplace health plan without their knowledge or consent, or switches plans without their knowledge or consent, that action can trigger Advance Premium Tax Credit (APTC) payments on behalf of a person who never actually agreed to the coverage — resulting in improper payments, because the subsidy is based on an eligibility determination tied to an application the enrollee did not knowingly submit or a plan the person did not select. These improper payments can result in the improper disbursement of taxpayer dollars. Accordingly, we propose to strengthen the integrity of the vetting and oversight processes for agents, brokers, and web-brokers participating in the FFEs and SBE-FPs to reduce waste, fraud, and abuse, protect Exchange consumers, and safeguard Exchange systems.

A. Statutory and Regulatory Authority

Section 1312(e) of the Patient Protection and Affordable Care Act (the Affordable Care Act) provides the Secretary with the authority to establish procedures under which a State may

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[171] *See supra note 3*. From 2023 through 2025, CMS received over 624,000 consumer complaints attesting to unauthorized enrollments or unauthorized plan switching in the Federally-facilitated Exchanges by agents or brokers and confirmed by issuer review; approximately 300,000 of the 624,000 consumer complaints were received in 2025 alone (web-brokers are excluded from this count).

allow agents or brokers to: (1) enroll qualified individuals and qualified employers in qualified health plans (QHPs) offered through Exchanges; and (2) assist individuals in applying for premium tax credits and cost-sharing reductions (CSRs) for QHPs sold through an Exchange. Section 1313(a)(5) of the Affordable Care Act provides that, with respect to activities carried out under Title I of the Affordable Care Act, the Secretary shall provide for the efficient and non-discriminatory administration of Exchange activities and implement any measure or procedure that— (A) the Secretary determines is appropriate to reduce fraud and abuse in the administration of Title I; and (B) the Secretary has authority to implement under Title I or any other Act. Section 1321 of the Affordable Care Act also authorizes the Secretary to issue regulations setting standards for meeting the requirements under Title I of the Affordable Care Act with respect to the establishment and operation of Exchanges (including Small Business Health Options Program), the offering of QHPs through such Exchanges, and such other requirements as the Secretary determines appropriate.

Regulations at 45 CFR 155.220 implement the statutory requirements in section 1312(e) of the Affordable Care Act, establishing standards governing Exchange participation by agents, brokers, and web-brokers, including Exchange Agreement(s) requirements, standards of conduct, and enforcement authorities. The proposals in this rule would revise these existing requirements and strengthen oversight, improve enforcement procedures, and better protect consumers and taxpayer dollars.

B. Overview of Proposed Policies

These proposed policies would improve CMS'[172] ability to prevent abusive conduct by agents, brokers, and web-brokers, better protect consumers within the FFEs and SBE-FPs, and support the efficient, non-discriminatory administration of the FFEs and SBE-FPs. First, this proposed rule would add participation standards to 45 CFR 155.220(g)(3) that would prevent

[172] Although 45 CFR 155.220 references "HHS," CMS is the agency taking the actions discussed, therefore "CMS" will be used throughout this preamble when referencing the agency administering this regulatory framework.

agents, brokers, and web-brokers from participating in the FFEs and SBE-FPs in the circumstances described below, which CMS believes present an unacceptable risk because continued participation may pose a substantial likelihood of consumer harm, improper enrollment activity, misuse of Exchange information, or material program integrity concerns (defined in section VI.B. of this proposed rule). Specifically, agents, brokers, and web-brokers that CMS determines pose such an unacceptable risk would not be permitted to register, complete training, or enter into agreements with the FFEs and SBE-FPs as described in § 155.220(d) (hereinafter referred to as "Exchange agreement(s)"), preventing them from assisting consumers with enrolling in Exchange coverage, including insurance affordability programs, through the FFEs and SBE-FPs. Additionally, this proposed rule would update § 155.220(g)(3) to allow CMS to immediately terminate agents, brokers, and web-brokers who the agency determines pose such an unacceptable risk from participating in the FFEs and SBE-FPs, without waiting 30 calendar days from the date of notice.

To strengthen oversight and improve fairness in enforcement proceedings arising from findings of agent, broker, and web-broker noncompliance under § 155.220(g)(2), we propose additional revisions to § 155.220. Specifically, we propose to amend § 155.220(g)(3)(i) to replace the existing opportunity for agents, brokers, and web-brokers to "resolve" a noncompliance determination with an opportunity to "refute" before CMS terminates their Exchange agreement(s) for cause or imposes other penalties. As discussed in section VI.C.1. of this proposed rule, this change would clarify that the 30-calendar day period is primarily for submitting information to dispute or rebut a noncompliance determination.

We also propose to codify the factors that CMS would consider when determining whether to terminate an agent, broker, or web-broker's Exchange agreement(s) with the FFEs and SBE-FPs for cause and to impose other penalties under § 155.220(k)(1) after making a noncompliance determination. In addition, we propose to amend § 155.220(h) to clarify that agents, brokers, or web-brokers may request reconsideration when CMS denies them the right to

enter into Exchange Agreement(s) in addition to when CMS terminates their Exchange Agreement(s) for cause.

We also propose to add a new standard in § 155.220(j) to codify a term in the existing FFEs and SBE-FP Exchange agreement(s) requiring agents, brokers, and web-brokers to implement and maintain reasonable safeguards to ensure that access and attempted access to the FFEs and SBE-FPs, systems that support the FFEs and SBE-FPs, and consumer personally identifiable information (PII) obtained through those Exchanges only occur from locations within the United States.

We have also determined changes to § 155.220(g)(5) are necessary and appropriate to enhance transparency measures (for example, the public registration termination list) around program integrity oversight of the FFEs and SBE-FPs and further strengthen our administrative actions against suspected bad actors. Specifically, this proposed rule would make several amendments to § 155.220(g)(5), including moving from a fraud-based standard to an abusive conduct-based framework. This proposed rule would also adjust the standard of proof CMS would apply to suspensions and terminations for cause of an agent, broker, or web-broker's Exchange agreement(s) under § 155.220(g)(5). Specifically, under § 155.220(g)(5)(ii), CMS could suspend an agent's, broker's, or web-broker's agreements if CMS finds that there is a credible allegation of abusive conduct. Under § 155.220(g)(5)(iii), CMS could terminate those agreements if CMS determines, by a preponderance of the evidence, that abusive conduct occurred. Furthermore, this proposed rule would amend § 155.220(j)(2)(i) and (ii) by adding illustrative, non-exhaustive examples of agent, broker, and web-broker behavior that CMS has observed and considers harmful. CMS would also amend § 155.220(j)(4) to limit its scope as applied to abusive conduct as proposed in § 155.220(g)(5)(1). We seek comment on these proposals.

C. Expand Authority to Deny and Terminate Agents, Brokers, and Web-brokers' Exchange Participation

There are certain instances in which participation by an agent, broker, or web-broker can pose an unacceptable risk to the FFEs and SBE-FPs, including when certain administrative actions have been taken by Federal programs and State licensure authorities, as well as when an agent, broker, or web-broker has been convicted of a Federal or State misdemeanor or felony offense that CMS determines is detrimental to the best interests of the FFEs, SBE-FPs, and their consumers. Similar authorities regarding providers or suppliers with felony convictions have long existed in the Original Medicare program, also known as Medicare fee-for-service.[173] Medicare suppliers and providers, as well as agents, brokers and web-brokers in the Exchange, are entrusted with safeguarding program integrity, public health, and taxpayer money. Better alignment between the Federal Exchange platform approach with similar longstanding authorities that exist in the Medicare program would create consistency and strength through a unified voice and are necessary to increase program integrity and better protect consumers and taxpayer dollars by preventing agents, brokers, and web-brokers that pose unacceptable risk from participating in the FFEs and SBE-FPs.

1. Suspension, Termination, or Debarment from Any Federal Program, or Suspension or Revocation of State Licensure in Any State (§ 155.220(g)(3)(iii))

We propose to add § 155.220(g)(3)(iii) to provide that CMS may deny registration for, or immediately terminate the Exchange Agreement(s) of, any agent, broker, or web-broker who is currently terminated, suspended, revoked, debarred, or excluded from participation in any Federal program, or whose license is currently revoked or suspended for conduct that may cause harm to consumers or program integrity in a State other than that in which the agent, broker, or web-broker is enrolling consumers, regardless of whether any appeals are pending. If the appeal is successful and no other grounds for denial of registration exist, CMS would allow the agent, broker, or web-broker to register (or re-register if they were terminated) with the FFEs and SBE-FPs. Agents, brokers, and web-brokers with a history of these adverse actions imposed by a

[173] 42 CFR 424.535(a)(3), 424.535(a)(19).

Federal program or a State licensing entity pose an unacceptable risk for the FFEs, SBE-FPs, and their consumers because they have demonstrated an inability to abide by the rules of other programs to such an extent that serious sanctions were warranted. Accordingly, if codified, we believe this proposal would better protect the FFEs, SBE-FPs, and consumers by preventing agents, brokers, and web-brokers who have a track record of misconduct from participating in the Exchange agent-broker program. We seek comment on the potential need for any exceptions to this proposed bar on participation, as well as if there are any reasons why an agent, broker, or web-broker who is currently terminated, suspended, revoked, debarred, or excluded from participation in a Federal program should not also be barred from participation in the FFEs and SBE-FPs. CMS also believes it is prudent to take such action even if an appeal, which can take months if not years to complete, is pending, and seeks public comment on whether any exceptions to this approach are warranted.

Additionally, CMS seeks comment on whether agents, brokers, and web-brokers who are terminated for noncompliance on the Exchanges should also be referred for nonprocurement suspension and debarment. HHS has adopted OMB's guidelines (2 CFR 180) for nonprocurement suspension and debarment at 2 CFR 376, but CMS does not currently refer terminated agents, brokers, and web-brokers for suspension or debarment.

Agents, brokers, and web-brokers enter into public agreements with the Federal Government in order to gain access to the Exchanges where they enroll consumers in QHPs and earn commissions on such enrollments. Such commissions are paid to these agents, brokers, and web-brokers by QHP issuers who, in turn, receive PTC subsidy funding from the Federal Government for eligible enrollments. Per 2 CFR 180.970, a nonprocurement transaction means any transaction, regardless of type (except procurement contracts), including, but not limited to, subsidies, § 180.970(a)(8), and insurances, § 180.970(a)(9). As specified in 2 CFR § 180.970(b) a nonprocurement transaction at any tier does not require the direct transfer of Federal funds.

Therefore, the actions of an agent, broker, or web-broker enrolling a consumer in a QHP could constitute nonprocurement transactions under this meaning and these regulations.

If CMS were to implement such a policy, when we have adequate evidence that there may be a cause for debarment of an agent, broker, or web-broker and conclude that immediate action is necessary to protect the Federal interest, we could impose a 12-month suspension and initiate proceedings for debarment. Because the standard of proof for pursuing debarment is the same as the standard of proof for pursuing termination (i.e., the preponderance of the evidence, 45 CFR 155.220(g)(2); 2 CFR 180.850(a)), CMS could impose suspension and consider debarment for all agents, brokers, and web-brokers that are terminated for noncompliance. Suspension could occur immediately upon effectuation of agent, broker, or web-broker termination. If such a termination were to be reversed upon reconsideration per 45 CFR § 155.220(h), then this suspension would be lifted. If such a termination were to be sustained upon reconsideration or no request for reconsideration were submitted, then proceedings for debarment could be initiated where the grounds for termination meets the criteria for debarment specified at 2 CFR 180.800(b)(2) (that is, a history of failure to perform or of unsatisfactory performance of one or more public agreements or transactions). Generally, debarment cannot exceed three years, however, if circumstances warrant, an agency may impose a longer period of debarment (2 CFR 180.865). If CMS were to implement such a policy, therefore, we could pursue a term of debarment that mirrors the length of the penalty imposed under 45 CFR § 155.220(k)(1)(i) (that is, the period that a terminated agent, broker, or web-broker may be denied the right to enter into agreements with the Exchanges in future years). If CMS were to implement such a policy, then updates to the forms completed by agents, brokers, and web-brokers (for example, OMB Control Nos. 0938-1204 and 0938-1463) as well as all relevant enforcement notices (for example, Notices of Intent to Terminate, Final Notices of Termination, and Final Agency Determinations after reconsideration) could be necessary. The Final Notice of Termination could constitute the Notice of Proposed Debarment (2 CFR 180.805), and the

process to appeal such nonprocurement suspension and debarment actions could occur through a process similar to that used to appeal the termination action (that is, the request for reconsideration under 45 CFR 155.220(h)).

We seek comment on all aspects of this discussion of nonprocurement suspension and debarment for agents, brokers, and web-brokers who are terminated for noncompliance on the Exchanges, including the potential need for any exceptions, as well as if there are any reasons why an agent, broker, or web-broker who is terminated should not be referred for non-procurement suspension or debarment.

In addition, while § 155.220(g)(3)(ii) already authorizes CMS to immediately terminate an agent, broker, or web-broker's Exchange Agreement(s) if the agent, broker, or web-broker fails to maintain the appropriate license in every State in which they actively assist consumers with applying for the APTC or enrolling in a QHP through the FFEs or SBE-FPs, no comparable regulatory authority currently exists to deny registration for, or terminate the agreement of, an agent, broker, or web-broker whose license has been suspended or revoked in a State in which the agent, broker, or web-broker is not currently enrolling consumers. This gap is problematic because health insurance license reciprocity derives from an agent, broker, or web-broker's resident State, and disciplinary actions in non-resident States may not affect an agent, broker, or web-broker's ability to continue to enroll consumers in other States. Under our current authority, an agent, broker, or web-broker whose license has been revoked for misconduct in one State could potentially continue enrolling consumers in QHPs through the Exchanges and pose a risk to consumers in other States where the agent, broker, or web-broker is still licensed. Under these proposed regulatory changes, we would be able to better protect consumers in States with FFEs or SBE-FPs from agents, brokers, or web-brokers that pose unacceptable risk due to their suspension or revocation of a license in a State where they are not enrolling consumers, or their suspension, termination, or debarment from a Federal program.

Also, we propose to update § 155.220(g)(3)(i), which currently provides agents, brokers, and web-brokers with 30 calendar days after the date of notice to rebut a noncompliance determination prior to termination. The update to § 155.220(g)(3)(i) would allow CMS to immediately terminate agents, brokers, and web-brokers that pose unacceptable risk from participating in the FFEs and SBE-FPs due to suspension, termination, or debarment from any Federal program, or suspension or revocation of State licensure in any State.

2. Misdemeanor and Felony Convictions (§ 155.220(g)(3)(iv))

We also propose to add § 155.220(g)(3)(iv) to provide CMS with the ability to deny registration to, or immediately terminate the agreement for cause with, any agent, broker, or web-broker who was convicted of a Federal or State misdemeanor or felony offense that HHS determines is detrimental to the best interests of the FFEs, SBE-FPs, or their consumers.

Similar authorities already exist with respect to felonies in the Original Medicare program related to provider and supplier enrollment.[174] Similar to the rationale for imposing these requirements in Original Medicare, we believe that certain misdemeanor and felony offenses indicate a history of conduct that could undermine the integrity of Exchange operations or Exchange information systems, or place consumers and their PII at heightened risk of harm. Codifying this change would also better align the FFEs and SBE-FPs participation standards with similar longstanding authorities that exist in the Original Medicare program, ensuring consistency across CMS programs.

We also propose adding 45 CFR 155.220(g)(3)(iv)(A)(1) through (4) to clarify that misdemeanor and felony offenses detrimental to the best interests of the FFEs, SBE-FPs and their consumers include, but are not limited in scope or severity to: (1) misdemeanor and felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted,; (2) financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud, identity theft, forgery, bribery, falsification or destruction of records,

[174] 42 CFR 424.530(a)(3); 42 CFR 424.535(a)(3).

receiving stolen property, making false statements or claims, violation of consumer protection laws, and other similar crimes for which the individual was convicted; (3) any misdemeanor or felony that places the FFE program or its consumers at immediate risk, such as a conviction for criminal neglect or misconduct; and (4) any misdemeanor or felony that would result in mandatory exclusion under section 1128(a) of the Act.[175] If CMS denies an agent, broker, or web-broker registration or terminates their Exchange agreement(s) under § 155.220(g)(3)(iv), CMS will provide the agent, broker, or web-broker with notice of the decision, and the agent, broker, or web-broker may request reconsideration as described under § 155.220(h). We also propose amending 45 CFR 155.20 to add a definition of "convicted," defining it to mean: (1) a judgment of conviction has been entered against an individual or entity by a Federal or State court, regardless of whether there is a post-trial motion or an appeal pending, or the judgment of conviction or other record relating to the criminal conduct has been expunged or otherwise removed; (2) a Federal, State, or local court has accepted a plea of guilty or *nolo contendere* or an Alford plea by an individual or entity; or (3) an individual or entity has entered into participation in a first offender, deferred adjudication or other program or arrangement where judgment of conviction has been withheld. This definition closely mirrors Medicare's definition of conviction. The underlying conduct is the primary risk; thus, this definition is intended to protect consumers medically and financially as well as the FFE's and SBE-FPs' program integrity. If the appeal is successful and no other grounds for denial of registration exist, CMS would allow the agent, broker, or web-broker to register with the Exchange.

In addition, we propose to update § 155.220(g)(3)(i) to include paragraph (g)(3)(iv) as an exception to the requirement of providing 30 calendar days from the date of notice prior to termination of the agreement. This would allow CMS to immediately terminate agents, brokers,

[175] Section 1128(a) of the Act calls for the mandatory exclusion of the following individuals and entities from participation in any Federal healthcare program: (1) conviction of program-related crimes; (2) conviction relating to patient abuse; (3) felony conviction relating to health care fraud; and (4) felony conviction relating to controlled substance.

and web-brokers who pose unacceptable risk from participating in the FFEs and SBE-FPs due to certain misdemeanor and felony convictions.

We believe these policies are appropriate and necessary to strengthen program integrity, better protect consumers and taxpayer dollars, and better align the FFEs and SBE-FPs with longstanding Medicare program integrity authorities. More specifically, these policies would strengthen the vetting and oversight processes for agents, brokers, and web-brokers participating in FFEs and SBE-FPs to reduce waste, fraud, and abuse; support transparency around program integrity oversight of the FFEs and SBE-FPs to further strengthen our administrative actions against suspected bad actors; better protect consumers and taxpayer dollars by preventing agents, brokers, and web-brokers that pose unacceptable risk from participating in the FFEs and SBE-FPs; and better align the Federal Exchange platform approach with similar longstanding authorities that exist in Original Medicare.

D. Strengthen CMS' Authority to Terminate an Agent, Broker, or Web-Broker for Cause

1. Opportunity to Refute Determinations of Noncompliance (45 CFR 155.220(g)(3)(i))

We propose to revise § 155.220(g)(3)(i) to provide agents, brokers, and web-brokers with an opportunity to refute determinations of noncompliance prior to the termination of their Exchange agreement(s) for cause[176] and imposition of other penalties under § 155.220(k)(1), which would replace the existing opportunity to "resolve" identified noncompliance. Specifically, we propose that, except as provided in proposed paragraphs (g)(3)(ii) through (g)(3)(iv),[177] when CMS issues a determination of noncompliance against an agent, broker, or web-broker in accordance with § 155.220(g)(1), CMS would provide the agent, broker, or web-broker with 30 calendar days to submit information to refute the non-compliance determination.

[176] Section 155.220(f) establishes the framework for an agent, broker, or web-broker to terminate an agent's, broker's, or web-broker's Exchange agreement(s) with HHS. We are not proposing any changes with respect to the terminations under § 155.220(f).

[177] *See* § 155.220(g)(3)(ii), which provides that HHS may immediately terminate Exchange Agreement(s) upon notice to the agent or broker if they fail to maintain the appropriate license under State law, and § 155.220(g)(3)(iii) and (iv) in this proposed rule, which propose additional exceptions and allows for immediate termination without any further opportunity to refute the noncompliance determination.

Further, we propose to provide that after reviewing any rebuttal evidence submitted, CMS may terminate the agent, broker, or web-broker's agreements required under §§ 155.220(d) and 155.260(b), for cause, if CMS determines, based on the evidence available to CMS, that a preponderance of the evidence establishes that noncompliance occurred. The failure to submit evidence to refute would not preclude CMS from making such a determination based on the evidence otherwise available to CMS. We also propose to make corresponding edits to the heading of paragraph (g) and to paragraphs (g)(3)(ii), (g)(4), (k)(1), and (k)(2) to reflect this change. For purposes of this provision, "refute" means to submit information, documentation, or explanation disputing or rebutting a determination of noncompliance, which CMS would consider in determining whether termination and imposition of other penalties is appropriate. This opportunity to refute would not apply to findings of abusive conduct as proposed to be defined at § 155.20 and subsequent enforcement actions carried out under proposed § 155.220(g)(5), discussed later in this preamble.

The current regulation at § 155.220(g)(3)(i) governing termination for cause of agent, broker, and web-broker Exchange agreement(s) in FFEs and SBE-FPs for noncompliance states that CMS will notify the agent, broker, or web-broker of the specific finding of noncompliance or pattern of noncompliance made under § 155.220(g)(1), and after 30 calendar days from the date of the notice, may terminate their Exchange agreement(s) if the matter is not resolved to the satisfaction of CMS. Many agents, brokers, and web-brokers have interpreted this 30-calendar day period to mean that if the agent, broker, or web-broker takes corrective action or makes assurances that they will maintain compliance moving forward, that CMS may not proceed with termination. This interpretation is not consistent with our original intent with this regulation: to take enforcement action, as appropriate, in response to noncompliance notwithstanding corrective action or assurances by the agent, broker, or web-broker.[178] Further, if agents,

[178] *See* Patient Protection and Affordable Care Act; Program Integrity: Exchange, SHOP, and Eligibility Appeals final rule (78 FR 54080).

brokers, and web-brokers continue to have this belief, they may not be incentivized to refrain from noncompliant behavior and may instead believe that they can correct it before they are subject to any negative consequences. Therefore, we are proposing to reframe the 30-calendar day period as a time for the agent, broker and web-broker to refute the noncompliance rather than resolve the noncompliance, to clarify that nothing prevents CMS from terminating an agent, broker, or web-broker's Exchange agreement(s) where the agency makes a finding of noncompliance, even if the agent, broker, or web-broker takes corrective action or makes assurances that they will maintain compliance moving forward. Compliance with all terms and conditions of Exchange agreement(s), any State law applicable to agents, brokers or web-brokers, and any Federal law, including HHS regulations implementing those laws, is required at all times under § 155.220. Further, CMS expects compliance at all times with CMS' regulatory enforcement framework.

Further, by framing the 30-calendar-day period primarily as a time to *resolve* the matter to CMS' satisfaction, agents, brokers, and web-brokers have expressed concerns that they cannot refute the noncompliance finding or determination prior to a termination action going into effect. Instead, they can only do so after a termination action goes into effect and the agent, broker, or web-broker is offered a reconsideration in accordance with § 155.220(h). This belief is based on an incorrect reading of the current regulatory text. The existing language at § 155.220(g)(3)(i) frames the 30-calendar-day period as a time to resolve the matter "to the satisfaction of HHS," which some agents, brokers, and web-brokers have interpreted as being limited to corrective action or assurances of future compliance rather than as a time to dispute the underlying findings of noncompliance. Because the current regulatory text does not explicitly specify this 30-calendar-day period as a time to refute whether noncompliance occurred, agents, brokers, and web-brokers have mistakenly concluded that the reconsideration process under § 155.220(h), which occurs after a termination action goes into effect, is their first meaningful chance to refute the findings themselves.

As such, we have seen that some agents, brokers, and web-brokers choose not to respond during the 30-calendar-day notice period but will request reconsideration to dispute the findings. The intent of the 30-calendar-day notice period is to provide agents, brokers, and web-brokers the chance to provide CMS with information to inform a decision on whether the alleged noncompliance actually occurred. Bypassing this 30-calendar-day period to engage with CMS subverts the intent of the review and enforcement processes and wastes the time and resources of both CMS and agent, broker, and web-broker. If agents, brokers, and web-brokers have information that can refute a noncompliance determination, and they submit that information within the 30-calendar-day period, CMS would be able to make more fully informed decisions on the front end of the process and reduce resources expended on imposing enforcement actions, conducting reconsideration reviews, and in some instances, rescinding previously imposed terminations. This would also protect agents, brokers, and web-brokers from interruptions to their ability to assist consumers with enrollment through the FFEs or SBE-FPs as a result of an avoidable termination that was imposed due, in part, to their failure to refute during the 30-calendar-day period.

While CMS may consider any actions the agent, broker, or web-broker has taken to address or correct the identified noncompliance, these actions alone may not be determinative of whether CMS may proceed to terminate an agent, broker, or web-broker's Exchange agreement(s) and impose a penalty other than termination. As explained in section VI.D.2. of this proposed rule, under proposed § 155.220(g)(1)(i), CMS may consider the nonexclusive factors identified in § 155.285(b)(1) and (2), to the extent relevant to the facts and circumstances of the particular case, to assess the nature and circumstances of the noncompliance and the impact of that noncompliance before deciding whether termination, another penalty under § 155.220(k)(1), or both are appropriate. This approach would preserve CMS' flexibility to account for unusual circumstances. For example, analysis under the non-exclusive factors would allow CMS to consider an individual's history with the FFEs and SBE-FPs, which could include

consideration of any proactive actions taken to address or correct identified noncompliance. CMS may determine, based on consideration of the factors proposed in section VI.D.2. of this proposed rule, that despite corrective action, the noncompliance warrants enforcement action under § 155.220(g)(1) and (k)(1).

In summary, by aligning the regulation text to clarify and mirror the original intent of the policy, this proposed approach would protect the integrity of the FFEs and SBE-FPs and the interests of consumers; clarify that agents, brokers, and web-brokers have an opportunity to refute findings of noncompliance before termination goes into effect or CMS imposes a penalty; and help to ensure that enforcement decisions are based on a complete and accurate assessment of the noncompliance. We seek comment on these proposals.

2. Factors CMS May Consider in Enforcement Determinations (45 CFR 155.220(g)(1)(i))

We propose to revise § 155.220(g)(1) and add a new paragraph at § 155.220(g)(1)(i) to specify how CMS would determine whether to terminate an agent, broker, or web-broker's Exchange agreement(s) and impose a penalty under § 155.220(k)(1) when CMS has made a determination of noncompliance under § 155.220(g)(1).

Specifically, we propose to remove the "sufficiently severe" language in § 155.220(g)(1) and replace it with a new framework under proposed § 155.220(g)(1)(i). The removal of the "sufficiently severe" language is intended to reduce ambiguity regarding what is sufficient to trigger termination and instead replace it with explicit factors CMS would consider that are clear and transparent. The proposed framework would provide that, except for terminations made in accordance with paragraphs (g)(3)(ii) through (g)(3)(iv) of this section, when CMS makes a noncompliance determination under paragraph (g)(1), CMS would consider the factors identified in § 155.285(b)(1) and (2) to the extent relevant to the facts and circumstances of each case, as well as any additional relevant factors supported by the evidence when it: (A) decides whether to terminate an agent, broker, or web-broker's Exchange agreement(s) for cause; or (B) selects

among the penalties identified in paragraph (k)(1) of this section, including the length of the penalty imposed under paragraph (k)(1)(i) of this section.

The factors listed under § 155.285(b)(1) and (2) are the factors that CMS has established for consideration in determining the amount of a civil money penalty (CMP) imposed against an individual for providing false or fraudulent information to an Exchange. CMPs, terminations, and the imposition of other penalties are all enforcement mechanisms that aim to address and correct noncompliance. Thus, utilizing these factors when making determinations on whether to terminate for cause an agent, broker, or web-broker's Exchange agreement(s) and the imposition of penalties other than terminations, when relevant, would help to ensure consistency throughout CMS' enforcement mechanisms. Use of a single, nonexclusive factor framework across related enforcement decisions would reduce divergence in factors considered, increase consistency in decision making, and promote transparency while preserving CMS' flexibility to terminate Exchange agreement(s) and impose other penalties when supported by the facts of the identified noncompliance. The factors listed under § 155.285(b)(1) and (2) reflect the considerations most relevant to the full range of noncompliance CMS has encountered in overseeing the FFEs and SBE-FPs and are expected to apply in the vast majority of enforcement actions. The nonexclusive nature of the list preserves CMS' flexibility to account for case-specific circumstances not captured by the codified factors. We propose that CMS would consider additional factors to the extent they are relevant to the particular case and supported by the evidence. These additional factors could include, but would not be limited to, failure to cooperate with CMS monitoring, audit, or enforcement activities, or the submission of incomplete, inaccurate, or misleading information to CMS.

As explained in section VI.C.1. of this proposed rule, if CMS were to find that a preponderance of available evidence supports a finding that an agent, broker, or web-broker violated a standard under this section, an applicable Exchange agreement term, or Federal or State law, and that such noncompliance justifies termination of the agent, broker, or web-broker's

Exchange agreement(s), or imposition of other penalties based on an assessment of the proposed factors in § 155.285(b)(1) and (2), CMS will make a refutable determination of noncompliance under § 155.220(g)(3)(i). In accordance with proposed § 155.220(g)(3)(i), following the 30-calendar-day refutation period, CMS would review all refutation evidence provided and reassess whether a preponderance of the evidence still supports a finding of noncompliance that, based on an assessment of the proposed relevant factors in § 155.285(b)(1) and (2), justifies termination or imposition of other penalties under § 155.220(k)(1) before moving forward. If the information provided does not refute the noncompliance, meaning that a preponderance of the evidence still supports the noncompliance determination based on CMS' assessment of the proposed factors in § 155.285(b)(1) and (2), CMS may proceed to terminate an agent, broker, or web-broker's Exchange agreement(s) and impose other penalties. This approach aligns with § 155.285(b)(1)(vii) that contemplates evaluating "any additional information provided by the individual to refute performing the violation."

Under this proposal, CMS would weigh both mitigating and aggravating facts, but would retain discretion to weigh the proposed factors as appropriate and would not be required to consider all of the factors in every case. CMS would only consider a factor listed in § 155.285(b)(1) and (2) if the factor is relevant to the noncompliance at issue and applicable to the facts and circumstances of the particular case, and would consider both the presence and absence of a relevant factor when making a termination decision and selecting penalties. For example, not all findings of noncompliance as described in § 155.220(g)(2) involve the disclosure of false or fraudulent information as referenced in § 155.285(b)(2)(v). A finding of noncompliance may instead involve, for example, an agent, broker, or web broker's failure to obtain or maintain required consumer consent documentation. Similarly, even if an agent, broker, or web-broker did not receive compensation associated with the violation as described in § 155.285(b)(1)(vi), or CMS is not able to determine whether the agent, broker, or web-broker received compensation, assessment of other relevant factors may still support termination and

imposition of a penalty other than termination. In such circumstances, CMS may determine that enforcement action is appropriate based on its assessment of the other factors relevant to the particular case. We have determined that codifying these factors would provide greater transparency into CMS' enforcement decision-making under § 155.220(g)(1) and reflect that enforcement determinations are based on the totality of the circumstances.

Section 155.285(b)(1) provides that CMS may take into account the nature and circumstances of the conduct, including, but not limited to: the number of violations; the severity of the violations; the individual's history with the Exchange, including any prior violations that would indicate whether the violation is an isolated occurrence or represents a pattern of behavior; the length of time of the violation; the number of individuals affected or potentially affected; the extent to which a person received compensation or other consideration associated with the violation; any documentation provided in any complaint or other information, as well as any additional information provided by the person alleged to have committed the violation to refute performing the violation; and whether other remedies or penalties have been imposed on the person alleged to have committed the violation for the same conduct or occurrence.

When considering the number of and length of time of violations, as described in § 155.285(b)(1)(i) and (iv), CMS may look at, among other things, the number of regulatory requirements the agent, broker, or web-broker violated; the number of times CMS identified the agent, broker, or web-broker violated such requirements; compliance with previously provided technical assistance; and for how long the agent, broker, and web-broker sustained the noncompliance. For example, if an audit or other oversight action results in findings of many instances in which an agent, broker, or web-broker failed to document consumer consent and eligibility application information review in accordance with § 155.220(j)(2)(iii) and (j)(2)(ii)(A) for a large number of different consumers and applications, CMS may consider this more significant than an audit that identifies only a few instances of failure to document consumer consent across a small number of consumers and applications.

Similarly, in considering an agent, broker, or web-broker's history with the Exchange, as described in § 155.285(b)(1)(iii), CMS would consider any previously identified violations of agency regulatory requirements, such as those described in §§ 155.220 and 155.221, to assess whether the violation is an isolated occurrence or represents a pattern of behavior. However, the absence of a documented history of noncompliance would not preclude CMS from taking enforcement action as appropriate, including termination of an Exchange agreement required under § 155.220(d), against an agent, broker, or web-broker. If, after assessment of the other factors described in § 155.285(b)(1) and (2), CMS determines that totality of the circumstances warrants enforcement action, CMS would retain authority to terminate the Exchange agreement required under § 155.220(d) and impose a penalty other than termination under § 155.220(k)(1), regardless of whether the agent, broker, or web-broker had a prior history of noncompliance.

In considering the severity of any identified noncompliance with regulatory requirements, as described in § 155.285(b)(1)(ii), CMS would assess the nature and degree to which the agent, broker, or web-broker violated the regulatory requirement(s) at issue, including the extent to which the violation departed from the applicable requirement and whether the documented facts reflect a partial or complete failure to meet the requirement. Using noncompliance with the consent documentation requirements at § 155.220(j)(2)(iii) as an example, CMS would likely consider less severe a procedural or technical noncompliance in which an agent, broker, or web-broker clearly obtained and documented consumer consent, but the documentation did not include an adequate description of the process by which the consumer or their authorized representative may rescind the consent, as required by § 155.220(j)(2)(iii)(B). This type of violation would likely be considered less severe because the documentation demonstrated that the consumer knowingly consented to the enrollment, which is the core purpose of the consent requirement, and the deficiency was limited to an incomplete description of a procedural right.

In contrast, CMS would likely consider noncompliance with regulatory requirements to be more severe if it impacted the enrollee's ability to provide actual, informed consent before the

agent, broker, or web-broker enrolled them in coverage through the FFEs or SBE-FPs, as we would not be able to determine if the consumer named on the application provided such consent. This uncertainty directly undermines the core purpose of the consent requirement to ensure that enrollments are made with the consumer's knowing and voluntary authorization. Another example of a severe violation might include an instance in which an agent, broker, or web-broker failed to document the name of the consumer or consumer's authorized representative providing consent to be enrolled, creating a situation where we cannot determine if the consumer named on the application provided consent to the agent, broker, or web-broker's assistance with this enrollment. As a further example, CMS would likely consider enrolling a consumer in a health plan without *any* documented evidence that the consumer authorized the enrollment to be a severe violation because, as previously described, the consent requirement is a fundamental safeguard that helps ensure enrollments and application updates are authorized by the consumer. Failure to obtain or maintain any consent documentation prevents CMS from verifying that consumer authorization was obtained, undermines the integrity of the FFE and SBE-FP enrollment process, and increases the risk of consumer financial and medical harm. Because maintaining adequate consent documentation is a condition of participation in the FFEs and SBE-FPs, agents, brokers, and web brokers are responsible for retaining records sufficient to demonstrate compliance.

In considering the number of individuals affected by the noncompliance, as described in § 155.285(b)(1)(v), for instances in which the number of affected individuals cannot be readily determined from the documented instances of noncompliance, CMS could, for example, consider the total number of applications submitted by the agent, broker, or web-broker during the relevant period to determine the number of affected individuals should findings suggest a pattern of noncompliance likely existed across a large portion of the agent, broker, or web-broker's book of business. CMS may also consider the nature of the noncompliance because certain types of noncompliance may affect a broader population of consumers than others. For example, if CMS

finds that an agent, broker, or web-broker engaged in misleading marketing in violation of § 155.220(j)(3), CMS may consider the potential reach and impact of the misleading marketing to estimate the number of people affected, including the number of advertisements publicly posted, the number and type of platforms on which the advertisements were posted, the length of time the postings were made public or how often they were posted, available information regarding consumer exposure or engagement, complaints or referrals that mention the misleading marketing, and any related application or enrollment activity. CMS would consider such information, as available and appropriate, in assessing the number of individuals potentially affected and may not necessarily presume that all individuals who may have been exposed to a misleading advertisement were actually impacted by the advertisement.

In considering the extent to which a person received compensation or other consideration associated with the violation as an aggravating factor, as described in § 155.285(b)(1)(vi), CMS could, for example, weigh whether an agent, broker, or web-broker received commissions from QHP issuers for enrollments the agent, broker, or web-broker assisted with or facilitated while engaging in noncompliance.

In considering any additional information provided by the agents, brokers, and web-brokers to refute performing the violation, as described in § 155.285(b)(1)(vii), CMS would consider any information the agent, broker, or web-broker submits to refute a determination of noncompliance as described in proposed § 155.220(g)(3)(i). CMS could consider events or conditions outside the control of the agent, broker, or web-broker that affected their ability to comply with applicable requirements, such as a natural disaster that limits the agent, broker, or web-broker's access to records described under § 155.220(j)(2)(ii) and (iii) requested during a compliance an investigation. However, CMS would not consider a claim that an agent, broker, or web-broker is unable to produce documentation requested during an investigation, for example, because it is maintained by a former employer, as a mitigating factor in assessing noncompliance with the requirements to produce documentation of consent or eligibility

application review upon request. This is because, as required in §§ 155.220(j)(2)(ii)(A)(3) and (j)(2)(iii)(D), the individual or entity that assists with or facilitates enrollment of qualified individuals, qualified employers, or qualified employees, in coverage in a manner that constitutes enrollment through a FFEs or SBE-FPs, or assists individuals in applying for APTC and CSRs for QHPs sold through a FFEs or SBE-FPs, is responsible for maintaining the required documentation and providing it to HHS upon request.[179]

Further, we clarify that § 155.285(b)(1)(viii), which provides that CMS may consider whether other remedies or penalties have been imposed for the same conduct or occurrence, would not prevent CMS from terminating an agent, broker, or web-broker's Exchange agreement(s) or imposing a penalty under § 155.220(k)(1) should CMS identify new conduct that constitutes noncompliance with regulatory requirements, even after previously identifying or imposing penalties for noncompliance with the same regulatory requirements. Repeated noncompliance could be viewed as an aggravating factor and may weigh in favor of more significant enforcement action, such as the imposition of other penalties under § 155.220(k)(1). However, CMS would evaluate each instance of noncompliance based on the facts and circumstances and the applicable factors described in § 155.285(b)(1).

Section 155.285(b)(2) provides that CMS may also consider the nature of the harm resulting from, or reasonably expected to result from, a violation, including but not limited to: whether the violation resulted in actual or potential financial harm, such as unexpected tax liabilities for an individual; whether there was actual or potential harm to an individual's reputation; whether the violation hindered or could have hindered an individual's ability to obtain health insurance coverage; whether there was actual or potential harm resulting from providing false or fraudulent information or from the improper use or disclosure of the information; and

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[179] *See 45 CFR 155.220(j)(2)(iii)(C). See also* CMS, *Frequently Asked Questions: Consumer Consent & Application Review Requirements*, Question 35 (Oct. 28, 2024) *available at* https://www.cms.gov/marketplace/agents-brokers/files/frequently-asked-questions-consumer-consent-application-review-requirements.pdf providing that an agent, broker, or web-broker must maintain documentation of consumer consent and review of eligibility application information for a minimum of 10 years for all Marketplace consumers even if they stopped working for their former employer.

whether any person received a more favorable eligibility determination for enrollment in a QHP or insurance affordability program, such as greater APTCs or CSRs than they would have been eligible for if the correct information had been provided. In the context of determining whether to terminate an agent's, broker's, or web-broker's Exchange agreement(s) and impose a penalty other than termination under § 155.220(k)(1), it would be within CMS' discretion to assess whether the identified noncompliance resulted in actual or potential financial harm to an individual applicant or to taxpayers should CMS find that the agent, broker, or web-broker's noncompliance resulted in payment of APTCs or CSRs on behalf of individuals who were ineligible or who did not consent to enrollment in coverage through the FFEs or SBE-FPs with the assistance of the agent, broker, or web-broker. CMS may also consider other circumstances in which the noncompliance resulted in, or created a significant risk of, financial harm to consumers or to the Federal Government, based on the facts and circumstances of the particular case.

We note that our proposal to cross-reference only § 155.285(b)(1) and (2) would adopt the nonexclusive factor list in § 155.285(b)(1) and (2) but would not incorporate the CMP procedures outlined in § 155.285(c) through (f) because those procedures apply only when CMS imposes CMPs under § 155.285 and there are existing adequate procedures under § 155.220(g) and (k) that govern terminations and the imposition of other penalties. For termination and other penalties for noncompliance under § 155.220(g)(1) and (2), excluding CMPs, CMS would continue to follow the procedures described in proposed § 155.220(g)(1) through (4) and (k), and, for CMPs, CMS would continue to follow the procedures in § 155.285(c) through (f). Further, if CMS makes a finding or determination by a preponderance of the evidence under § 155.220(g)(5)(iii), CMS would terminate an agent's, broker's, or web-broker's Exchange agreement(s) and impose any penalties deemed appropriate consistent with that provision. For suspensions under § 155.220(g)(5)(ii), CMS would evaluate any rebuttal evidence submitted during the suspension period. The factor list would not apply to the suspension decision.

Additionally, in cases that fall under § 155.220(g)(3)(ii) and proposed paragraphs (g)(3)(iii) and (iv), CMS may immediately terminate Exchange agreements and impose additional penalties without the 30-day notice period in § 155.220(g)(3)(i) or consideration of the factor list.

When the factor assessment would apply to selection of penalties and CMS determines that it is appropriate to impose a denial of the right to enter into Exchange agreement(s), we are proposing that the length of such denial would be based on the totality of the circumstances and an assessment of the proposed factors. For example, denial of the right to enter future agreements for one year may be appropriate for violations with several mitigating factors or of lesser severity, such as deficiencies limited to an incomplete description of a procedural right rather than a failure to obtain or record meaningful consumer consent. More severe noncompliance and violations with several aggravating factors, such as noncompliance that likely impacted the enrollee's ability to provide actual, informed consent before the agent, broker, or web-broker enrolled them in coverage, would generally support a longer denial of right to enter into agreements with the FFEs and SBE-FPs. While the duration of the denial of right to enter into agreements with the FFEs and SBE-FPs would vary based on the totality of the circumstances and evidence, denial for a period of 10 years or more may be appropriate for the most severe violations with several aggravating factors. We also propose a conforming revision to § 155.220(g)(3)(ii) to replace the phrase "without any further opportunity to resolve the matter" with "without any opportunity to refute a finding of noncompliance under § 155.220(g)(1)," consistent with the proposed revisions to the refutation process under § 155.220(g)(3)(i). In addition, as an alternative, instead of cross referencing the factors in § 155.285(b), CMS is considering reproducing or adapting relevant factors from § 155.285(b) directly into § 155.220 in the final rule. Should CMS finalize regulatory text that reproduces or adapts relevant factors from § 155.285(b) directly into § 155.220, such a list would be nonexclusive and not all factors would apply in every case, as described in this proposal. We

invite comment on which factors identified in this proposal should apply and how they should be adapted for § 155.220, if at all. We seek comment on these proposals.

3. Clarification on the Scope of an Agent, Broker, or Web-Broker's Right to Request Reconsideration (45 CFR 155.220(h)(1))

We propose to revise 45 CFR 155.220(h)(1) to state that an agent, broker, or web-broker may request a reconsideration of CMS' decisions to terminate their Exchange agreement(s), deny registration under proposed § 155.220(g)(3)(iii) or (iv), or impose a penalty described in § 155.220(k)(1)(i) in the manner and form established by CMS.

Section 155.220(h)(1) currently provides agents, brokers, and web-brokers with the opportunity to request a reconsideration when HHS terminates an agent, broker, or web-broker's Exchange agreement(s), but does not explicitly address whether agents, brokers, and web-brokers are afforded the same reconsideration opportunity when HHS denies registration under proposed § 155.220(g)(3)(iii) or (iv), or imposes penalties other than termination under § 155.220(k)(1)(i). For example, if CMS determines that an agent, broker, or web-broker has failed to comply with the requirements in § 155.220, CMS may deny the agent broker, or web-broker the right to enter into Exchange agreement(s) as a penalty other than termination under § 155.220(k)(1)(i). Therefore, we propose in § 155.220(h)(1) to outline three instances in which an agent, broker, or web-broker may request reconsideration in the manner and form established by CMS. First, proposed § 155.220(h)(1)(i) would allow an agent, broker, or web-broker to request reconsideration of CMS' decision to terminate the agent, broker, or web-broker's Exchange agreement(s) under § 155.220(g). Second, proposed § 155.220(h)(1)(ii) would allow an agent, broker, or web-broker to request reconsideration of CMS' decision to deny registration with the Exchange under § 155.220(g)(3)(iii) or (iv). Third, proposed § 155.220(h)(1)(iii) would allow an agent, broker, or web-broker to request reconsideration of CMS' decision to impose a penalty under paragraph (k)(1)(i).

We believe this proposal would help ensure consistency in the application of reconsideration opportunities by expressly providing agents, brokers, and web brokers with the same opportunity to request reconsideration regardless of whether CMS terminates an Exchange agreement, denies registration, or imposes a penalty under 45 CFR 155.220(k)(1)(i). We also believe this would provide greater clarity and predictability regarding the availability of reconsideration and promote uniform administration of CMS' enforcement process.

Along those same lines, we also propose corresponding changes to § 155.220(g)(6) to clarify that CMS would notify the applicable State Department(s) of Insurance or other State agent or broker licensing authority whenever CMS imposes penalties other than termination under § 155.220(k)(1)(i), in addition to suspensions or terminations as stated in the current regulation. Because agents and brokers are licensed and regulated by States, such notifications support coordination between Federal and State regulators and enable State licensing authorities to evaluate whether additional action under State law is appropriate.

Furthermore, we clarify the nature and scope of the existing reconsideration process. Operationally, the form and manner currently specified by CMS is that requests for reconsideration must be handled independently by a separate administrative unit of CMS than that which imposed the original penalty. Specifically, CMS' Center for Consumer Information and Insurance Oversight (CCIIO) and Center for Program Integrity (CPI) handle investigations and imposition of penalties, while CMS' Office of Program Operations and Local Engagement (OPOLE) handles requests for reconsideration. OPOLE adjudication of requests for reconsideration constitutes a *de novo* review of the enforcement action based on the totality of the facts and circumstances of the particular case, including potentially exculpatory information submitted by the agent, broker, or web-broker and verification that all internal CMS enforcement policies and procedures were followed. OPOLE evaluates whether the preponderance of the evidence supports the enforcement action. OPOLE administration of requests for reconsideration generally result in one of three outcomes: sustaining the enforcement action,

reversing the enforcement action, or modifying the enforcement action (for example, reducing the duration of the termination imposed).

We seek comment on this proposal.

4. Policies to Address Abusive Conduct

a. Purpose and Description of Abusive Conduct Standards

Abusive conduct by agents, brokers, and web-brokers can adversely impact consumers, resulting in significant medical or financial harm. Consumers enrolled in Exchange QHPs without their knowledge or consent can experience interruptions in access to medical care and unexpected tax liabilities associated with receiving APTCs. Through our investigations and data analytics in the FFEs and SBE-FPs, we have identified specific actions and patterns of inappropriate behavior by agents, brokers, and web-brokers that violate the standards of conduct listed in § 155.220(j)(2). These activities ultimately result in consumers being misled about important aspects of their Exchange coverage, including their eligibility for APTC based on their income, the cost-sharing implications (that is, deductibles and copayments) associated with the insurance plans they sign up for, and other material information necessary to make informed enrollment decisions.

Through our investigations of consumer complaints and analyses of enrollment activity in the FFEs and SBE-FPs, we have found that significant consumer harm arises from abusive conduct by agents, brokers, and web-brokers that may not initially rise to the level of fraud under current § 155.220(g)(5). The proposed standard of abusive conduct would better reflect the nature of the misconduct we are seeing that often involves deceptive or coercive enrollment practices, material misrepresentations, unauthorized application or enrollment activity, or the submission of inaccurate application information that misleads consumers and undermines the integrity of Exchange operations. Under the current regulatory framework, the suspension authority at § 155.220(g)(5) is tied in part to a reasonable suspicion of fraud, which may not capture a significant portion of the types of misconduct CMS encounters through its Marketplace

oversight activities. Based on this experience, we have determined it is appropriate to propose revising our regulations to establish an enforcement framework that would more directly address the misconduct we are seeing while applying a clear and transparent evidentiary standard.

Accordingly, we believe revisions to our suspension and termination authorities are necessary to better align our enforcement authorities with the types of abusive conduct encountered through our Marketplace oversight. We therefore propose to amend § 155.220(g)(5) by removing reference to a "reasonable suspicion of fraud" in § 155.220(g)(5) and replacing it with a standard under which CMS may suspend an agent, broker, or web-broker when CMS finds there exists a credible allegation of abusive conduct by the agent, broker, or web-broker. We further propose amending § 155.20 to add a definition of "a credible allegation of abusive conduct," defining it to mean: an allegation from any source, including but not limited to the following: (1) consumer, Marketplace call center, or agent, broker, or web-broker complaints verified by further evidence; (2) data or information identified during investigation; or (3) patterns identified through data analysis. Additionally, the definition would state that allegations are considered to be credible when they have indicia of reliability. The presence of one of these sources alone could be sufficient to meet this standard as a credible allegation of abusive conduct, depending on the facts of each individual case.

Unlike a general finding of noncompliance or pattern of noncompliance under § 155.220(g)(1) and (2), enforcement actions under § 155.220(g)(5) would apply to the most egregious behaviors. Specifically, enforcement actions would apply when the conduct is likely to or has caused harm to the Federally facilitated Exchange, SBE-FP, or their consumers. Conduct that does not meet this harm standard, though it may cause harm, would be addressed through enforcement actions authorized under § 155.220(g)(1) through (3). We seek comment on this proposal.

Likewise, we propose to amend § 155.220(g)(5)(ii) and (iii) to establish standards for suspension and termination based on a finding of abusive conduct. Specifically, we propose that

CMS may suspend an agent, broker, or web-broker based on a credible allegation of abusive conduct and may terminate the agreement of an agent, broker, or web-broker based on a preponderance of evidence of abusive conduct. We believe the proposed credible allegation of abusive conduct standard for suspensions is consistent with Medicare's payment suspension authority, which uses a credible allegation of fraud standard, and mirroring these standards is appropriate because the resulting impact is similar between a Marketplace suspension and Medicare payment suspension. We believe the proposed preponderance of the evidence standard for terminations is appropriate because it is the evidentiary standard generally applied in Federal administrative and civil cases, and it would create a fair, well-established, and transparent basis for final enforcement actions. Adopting these standards would better align our enforcement framework with the nature of these administrative proceedings while providing agents, brokers, and web-brokers with greater clarity regarding the evidentiary standard CMS would apply when determining whether termination is warranted. This proposal would also align with the standards we have used for other enforcement actions against agents, brokers, and web-brokers. We seek comment on these standards and alternative standards that could be used for suspensions and terminations.

We also propose to amend § 155.220(g)(5)(i) to define abusive conduct as any conduct that is likely to cause or has caused harm to the Exchange or its consumers that includes, but is not limited to: (1) a violation of the standards of conduct at 45 CFR 155.220(j)(2); (2) providing the Exchange with inaccurate application information related to the consumer's eligibility for Medicaid, CHIP, a QHP offered through the Exchange, advance premium tax credit, or cost-sharing reductions; or (3) a violation of any term or condition of the agreements with the Exchange that relates to the agent, broker, or web-broker's conduct toward consumers.

This would incorporate the proposed examples of violations of the existing standard of conduct to provide consumers with correct information by adding § 155.220(j)(2)(i)(A) and (B) These include:

● Having a website that HHS determines could mislead a consumer into believing the consumer is visiting *HealthCare.gov,* an official Marketplace, Affordable Care Act or Exchange enrollment website, certified Exchange enrollment partner website, or any other official website of the Federal or a State government. To do this, we would move the existing parenthetical in the current § 155.220(j)(2)(i) that states: "including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*" to a new paragraph (A).

● Falsely claiming to represent the FFE or SBE-FPs or falsely suggesting that coverage from the FFE or SBE-FP is free. We would do this by creating a new paragraph (B).

The proposed definition of abusive conduct at § 155.220(g)(5)(i) would also incorporate the proposed amendments to § 155.220(j)(2)(ii)(E) through (K):

● Paragraph (E)*(1)* would state: An agent, broker, or web-broker may not project, or mislead or coerce a consumer to project, one of the following:

++ An annual income that is not based on any actual or reasonably expected source of income.

++ Income the consumer is unlikely to earn.

++ Income that omits one or more tax household members.

++ Income based on inappropriate modified adjusted gross income calculations, such as projecting income based on income after income tax withholding.

++ A predetermined income amount that the consumer is coached, targeted, or steered towards by the agent, broker, or web-broker.

● Paragraph (F) would provide state: Submitting application and enrollment data only for consumers who are not deceased at the time of enrollment.

● Paragraph (G) would state: Accurately entering information provided and confirmed by the consumer pertaining to any existing minimum essential coverage as defined by 45 CFR part 156 Subpart G, that the consumer is eligible for or enrolled in.

- Paragraph (H) would state: Accurately entering information provided and confirmed by the consumer pertaining to all tax household members. Agents, brokers, and web-brokers must ask consumers about their household composition to the same extent consumers are asked about household composition on the Exchange eligibility application and accurately report each consumer response.

- Paragraph (I) would state: Accurately entering information provided and confirmed by the consumer regarding residence address in accordance with § 155.305(a)(3).

- Paragraph (J) would state: Accurately entering information provided and confirmed by the consumer regarding household contact information including names, phone number and mailing address, and if the consumer chooses to provide them, accurate email address and mobile phone number for text messages. Consumer contact information must only be the consumer's personal contact information and cannot be contact information accessible or controlled by an agent, broker, web-broker or any other non-consumer persons or entities.

- Paragraph (K) would state: Using customer service channels that HHS determines do not mislead a consumer into believing the consumer is providing information to or enrolling through an official Exchange, Marketplace, or Affordable Care Act customer service pathway or representative, or through certified Exchange enrollment partners.

In addition, we propose to amend § 155.220(j)(4) to provide that conduct resulting solely from inadvertent error notwithstanding reasonable compliance measures does not constitute abusive conduct. We believe the abusive conduct under § 155.220(g)(5)(i) poses an unacceptably high risk to the Exchanges and their consumers. Therefore, conduct resulting solely from an inadvertent error, notwithstanding reasonable compliance measures, does not rise to the level of unacceptable high risk for abusive conduct. In cases where abusive conduct is credibly alleged or found, regardless if an agent, broker, or web-broker has and follows reasonable compliance measures to prevent abusive conduct, CMS would still take suspension and/or termination action under § 155.220(g)(5) given the likelihood of harm arising from such conduct.

We have provided a non-exhaustive list of examples of conduct that would fall into this category later in this proposed rule as part of our proposed changes to § 155.220(j)(2), below. This would ensure CMS retains the ability to take appropriate enforcement action against conduct that poses a high risk to the Exchanges and their consumers.

We also propose to amend the rebuttal review period within § 155.220(g)(5) from 45 calendar days to at least 60 calendar days to allow CMS more time to review submitted evidence and make a more informed decision. Under proposed § 155.220(g)(5)(ii)(B), agents, brokers, and web-brokers subject to suspension in accordance with § 155.220(g)(5) would have 30 calendar days to submit rebuttal evidence after which CMS would review that evidence and make a determination on lifting the suspension or pursuing termination in accordance with § 155.220(g)(5)(iii) within 90 calendar days of the suspension. This would provide CMS at least 60 calendar days for review of evidence submitted by an agent, broker, or web-broker as such evidence must be submitted within the first 30 days of the 90-day suspension period.

We further propose to simplify the structure of § 155.220(g)(5) to more clearly delineate the authorities to suspend or terminate an agent, broker, or web-broker's Exchange Agreements.

While we outline specific behaviors that would be considered abusive conduct, we do not intend for these examples to be an exhaustive list. Rather, we propose at new § 155.220(g)(5)(i)(D) that CMS would maintain the discretion to evaluate each case individually to determine if it is otherwise misleading or coercive conduct that constitutes abusive conduct. This would allow the agency to address unique or novel forms of misleading or coercive behavior that should constitute abusive conduct

We believe these proposed program integrity measures are necessary and appropriate to promote greater transparency in CMS' oversight of agents, brokers and web-brokers participating in the FFEs and SBE-FPs, as well as support more effective and efficient administration of the FFEs and SBE-FPs, for the reasons stated earlier in this section of this proposed rule. We seek comment on these proposals, as well as any other fact patterns that may

be indicative of abusive conduct for which it would be appropriate for us to take enforcement under § 155.220(g)(5). We also seek comment on how CMS can improve transparency around the noncompliance and abusive conduct enforcement action processes.

b. Non-Exhaustive List of Examples of Abusive Conduct

We believe the following behaviors rise to the level of abusive conduct under proposed revisions to § 155.220(g)(5), subjecting an agent or broker to potential suspension and termination. We are providing these examples in the interest of transparency for agents, brokers, and web-brokers. This is a non-exhaustive list of behaviors, and CMS would retain the ability to take suspension and termination action based on any other misleading or coercive conduct it identifies through the course of an investigation, as proposed in new § 155.220(g)(5)(i)(D).

(1) Violation of Standards of Conduct

As noted above, we propose at § 155.220(g)(5)(i)(A) that abusive conduct includes a violation of the standards of conduct at 45 CFR 155.220(j)(2) Under current § 155.220(j)(2)(i) and (ii), agents, brokers, and web-brokers must provide consumers with correct information, without omission of material fact, regarding the FFEs and SBE-FPs, QHPs offered through the FFEs and SBE-FPs, and insurance affordability programs. Agents, brokers, and web-brokers must also refrain from conduct that is misleading or coercive and must provide the FFEs and SBE-FPs with correct information. We propose to amend § 155.220(j)(2)(i) and (ii) to specify types of behavior we consider to be misleading or coercive to make it easier for agents, brokers, and web-brokers to comply with the standards of conduct.

We propose to amend § 155.220(j)(2)(i) by moving the existing parenthetical that states "including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*" to a new paragraph (A) and updating the list of websites to include other official websites such as Marketplace websites other than HealthCare.gov and other official website of the Federal or State government. We also propose

to create a new paragraph (B) to specify that falsely claiming to represent the FFEs and SBE-FPs or suggesting Exchange coverage is free would constitute misleading or coercive behavior.

Specifically, we propose that agents, brokers, and web-brokers that fail to provide consumers with material facts or otherwise provide consumers with incorrect, misleading, or coercive information that impedes a consumer's ability to make an informed decision regarding their eligibility and enrollment in the FFEs SBE-FPs would be considered to engage in misleading or coercive conduct. This may include, but is not limited to (1) agents, brokers, and web-brokers misrepresenting themselves as agents of the FFEs and SBE-FPs (or similarly, the Marketplace, HealthCare.gov, Affordable Care Act, Exchanges), Medicaid, or Medicare; or (2) inaccurately suggesting to consumers that coverage on the Exchange is free.

As to the latter, even in situations where the consumer has a $0 net premium after the application of APTC, agents, brokers, and web-brokers must accurately communicate applicable deductibles, cost sharing, and other material costs to the consumer, and explain that APTC is an advanced payment based on projected income that may require repayment based on actual income, upon filing a Federal income tax return and reconciling APTC. We consider these examples to constitute abusive conduct because they are likely to cause harm to consumers or the Exchange. For example, when consumers wrongly believe that the agent, broker, or web-broker that is calling them represents an Exchange, they are unaware of the commission payment incentives that may steer them toward a specific plan or product. As another example, when consumers are misled into believing that coverage on the FFEs and SBE-FPs is free, they may be financially harmed when they are charged a deductible, copayment, and coinsurance, of if they are required to repay excess APTC. For consumers whose incomes are too low for APTC eligibility, the Exchanges are harmed by the outflow of millions of dollars in APTC subsidies that are not authorized by law nor capable of recoupment.

(2) Inaccurate Information on the Exchange Eligibility Application

Agents, brokers, and web-brokers that provide materially inaccurate information on the Exchange eligibility application, either knowingly or by failing to ask the consumer all questions on the eligibility application, may be subject to suspension and termination for abusive conduct consistent with these proposed revisions to § 155.220(j)(2)(ii). From investigations into agent, broker, and web-broker misconduct on the Exchanges, we have identified these behaviors as likely to cause harm to consumers or to the Exchanges. For example, enrollment of deceased individuals harms the Exchanges through the outflow of subsidy payments that are not authorized by law. In another example, entering incorrect address or contact information regularly causes consumer harm by creating insurance policies covering people who may already have coverage (introducing administrative burdens and access-to-care issues for consumers from processing coordination of benefits) or by keeping a consumer ignorant of a policy that has been created on their behalf and for which the consumer will be expected to pay back APTC payments in excess of their eligibility after filing for their income tax return. Similarly, entering incorrect information about household composition or residence is likely to cause an inaccurate APTC eligibility calculation that can result in unexpected financial losses for consumers when reconciling their APTC eligibility as part of the income tax filing process. We propose to amend the following regulations by adding examples to clarify types of behavior that are not permitted to make it easier for agents, brokers, and web-brokers to understand how to comply with the standards of conduct. We propose amending § 155.220(j)(2)(ii) as follows:

- Adding § 155.220(j)(2)(ii)(E)*(1)* that states: An agent, broker, or web-broker may not use or project, or ask a consumer to use or project, on the Exchange eligibility application the following:

++ An annual income that is not based on any actual or reasonably expected source of income.

++ Income the consumer is unlikely to earn.

++ Income that omits one or more tax household members.

++ Income based on inappropriate modified adjusted gross income calculations, such as projecting income based on income after income tax withholding.

++ A predetermined income amount that the consumer is coached, targeted, or steered towards by the agent, broker, or web-broker.

- Creating a new paragraph (F) that states: Submitting application and enrollment data only for consumers who are not deceased at the time of enrollment.

- Creating a new paragraph (G) that states: Accurately entering information provided and confirmed by the consumer pertaining to any existing minimum essential coverage as defined by 45 CFR part 156 Subpart G, that the consumer is eligible for or enrolled in.

- Creating a new paragraph (H) that states: Accurately entering information provided and confirmed by the consumer pertaining to all tax household members. Agents, brokers, and web-brokers must ask consumers about their household composition to the same extent consumers are asked about household composition on the Exchange eligibility application and accurately report each consumer response.

- Creating a new paragraph (I) that states: Accurately entering information provided and confirmed by the consumer regarding residence address in accordance with 45 CFR 155.305(a)(3).

- Creating a new paragraph (J) that states: Accurately entering information provided and confirmed by the consumer regarding household contact information including names, phone number and mailing address, and if the consumer chooses to provide them, accurate email address and mobile phone number for text messages. Consumer contact information must only be the consumer's personal contact information and cannot be contact information accessible or controlled by an agent, broker, web-broker or any other non-consumer persons or entities.

Each of these is described in more detail below.

(3) Enrollment in Other Health Coverage

We propose in 45 CFR 155.220(j)(2)(ii)(G) that agents, brokers, and web-brokers must enter information provided and confirmed by the consumer pertaining to any existing minimum essential coverage). From reviewing call recordings during investigations, we have identified many agents, brokers, or web-brokers that consistently failed to ask consumers whether they are eligible for, or already enrolled in, minimum essential coverage as defined by 45 CFR part 156 Subpart G (such as Medicaid, Medicare, employer-sponsored health coverage that meets the minimum value and affordability standards, or Veteran's Administration (VA) coverage). Additionally, we have identified many agents, brokers, and web-brokers that consistently only asked consumers whether they are eligible for, or enrolled in, a few types of minimum essential coverage, such as Medicaid or Medicare, and then inaccurately attested on the Exchange eligibility application that the consumers were neither eligible for, nor already enrolled in, any minimum essential coverage.

Under § 155.305(f)(1)(ii)(B), consumers are not eligible for APTC if they are eligible for minimum essential coverage for the full calendar month for which APTC will be paid, with the exception of coverage in the individual market, in accordance with 26 CFR 1.36B-2(a)(2) and (c). Under 45 CFR 155.220(j)(2)(ii) and (v), agents, brokers, and web-brokers must provide the Exchanges with correct information and comply with all applicable Federal and State laws and regulations. When agents, brokers, and web-brokers submit Exchange eligibility applications that include inaccurate attestations by consumers that they are not eligible for, or enrolled in, existing minimum essential coverage, consumers dually enrolled in Exchange coverage with APTC and other minimum essential coverage may be subject to significant medical or financial harm. For example, consumers dually enrolled in Exchange coverage with APTC and Medicaid may be confronted with unexpected administrative requirements and delays to using their benefits and determining which payer is appropriate for a service or drug that they require. Consumers can also be confronted with unexpected and confusing procedures for addressing coordination of benefits issues, which may ultimately lead to forgoing or delaying medical care.

We have observed this pattern in consumer complaints received by the Marketplace. Thus, we propose in § 155.220(j)(ii)(G) that agents, brokers, and web-brokers must accurately enter information provided and confirmed by the consumer pertaining to any existing minimum essential coverage as defined by 45 CFR part 156 Subpart G, that the consumer is eligible for or enrolled in, and that failure to do so may result in suspension or termination for abusive conduct consistent with these proposed revisions to § 155.220(g)(5).

(4) Inaccurate or Implausible Income Projections

We propose in 45 CFR 55.220(j)(2)(ii)(E)(*1*) that an agent, broker, or web-broker may not use or project, or ask a consumer to use or project, on the Exchange eligibility application, the following: (a) An annual income that is not based on any actual or reasonably expected source of income; (b) Income the consumer is unlikely to earn; (c) Income that omits one or more tax household members; (d) Income based on inappropriate modified adjusted gross income calculations; or (e) A predetermined income amount that the consumer is coached, targeted, or steered towards by the agent, broker, or web-broker; and doing so may result in suspension and termination for abusive conduct consistent with these proposed revisions to § 155.220(j)(2)(ii)(E)(*1*).

The information included on the Exchange eligibility application is used to determine and assess eligibility for Medicaid and CHIP, as well as eligibility for QHP coverage and APTC, based, in part, on a consumer's income. Accurate income projection is therefore essential in establishing whether an individual is eligible for APTC in any given month, taking into account a variety of factors. For example, consumers are not eligible for APTC if they are eligible for Medicaid for the full calendar month for which APTC will be paid, in accordance with 26 CFR 1.36B-2(a)(2) and (c). In accordance with 42 CFR 435.603(h)(1), financial eligibility for Medicaid must be based on the current monthly household income and family size, while pursuant to 26 CFR 1.36B-1(e)(1), income for purposes of APTC determinations generally includes the sum of a taxpayer's modified adjusted gross income, plus the aggregate modified

adjusted gross income of all other individuals who are included in the taxpayer's family and are required to file a return of tax for the taxable year. Under our regulations at 45 CFR 155.220(j)(2)(ii) and (v), agents, brokers, and web-brokers must provide the FFEs and SBE-FPs with correct information, only enter a consumer's household income projection that the consumer or the consumer's authorized representative designated in compliance with § 155.227 has knowingly authorized and confirmed as accurate, and comply with all applicable Federal and State laws and regulations.

Our investigations have shown that some Exchange eligibility applications submitted by agents, brokers, and web-brokers include inaccurate or implausible income projections that appear designed to avoid Medicaid and CHIP eligibility and secure APTC eligibility, while increasing the amount of APTC for which a consumer is eligible.[180] Specifically, agents, brokers, and web-brokers are encouraging consumers to agree to inaccurate or implausible household income by projecting, or asking consumers to project (1) an annual income that is not based on any actual or reasonably expected source of income (for example, asking unemployed consumers who would have no income to report projected income they could earn if they potentially find a job by the end of the year, rather than indicating on the eligibility application that the consumer is currently unemployed with no income); (2) income the consumer is unlikely to earn (for example, annual income based on an unrealistic amount of overtime for a part-time employee); (3) income that omits one or more household members; (4) income based on inappropriate modified adjusted gross income calculations (for example, the consumer reports their income after taxes); or (5) reporting a predetermined income amount that is suggested or targeted by the agent, broker, or web-broker and does not reflect the consumer's actual or reasonably expected annual income (for example, reporting income much lower than actual income to increase APTC).

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[180] *United States v. Cory Lloyd and Steven Strong*, No. 9:25-cr-80015 (S.D. Fl. Nov. 17, 2025). *CMS proposes regulations to lower health care costs, expand consumer choice, and protect taxpayers*. CMS. (n.d.). *https://www.cms.gov/newsroom/press-releases/cms-proposes-regulations-lower-health-care-costs-expand-consumer-choice-protect-taxpayers.*

Our proposed § 155.220(j)(2)(ii)(E)(*1*) would not require agents, brokers, or web-brokers to independently determine the accuracy of the consumer's own income projection. This provision also would not prohibit income projections made by consumers on a reasonable factual basis. For example, a consumer who is unemployed at the time of application may reasonably anticipate income from a position where they have accepted employment and will begin later in the year. However, this provision is intended to prevent an agent, broker, or web-broker from using or projecting, or asking a consumer to use or project, an income that lacks a reasonable factual basis.

We believe these types of inaccurate or implausible income projections reflect abusive conduct by agents, brokers and web-brokers because they can result in significant financial or medical harm to consumers. Dual enrollment may also confront consumers with unexpected and confusing procedures for addressing coordination of benefits issues, which may ultimately lead to forgoing or delaying needed medical care.

Thus, we propose to consider situations where agents, brokers, and web-brokers use or project, or ask a consumer to use or project, on the Exchange eligibility application, inaccurate or implausible income projections, to constitute abusive conduct that can trigger the suspension and termination of the agent, broker or web-broker's Exchange Agreement(s) under these proposed revisions to 45 CFR 155.220(g)(5).

(5) Inaccurate Household Compositions

We propose in 45 CFR 155.220(j)(2)(ii)(H) that an agent, broker, or web-broker must accurately enter information provided and confirmed by the consumer pertaining to all tax household members. We also propose that agents, brokers, and web-brokers must ask consumers about their household composition to the same extent consumers are asked about household composition on the Exchange eligibility application and accurately report each consumer response, and that failure to do so may result in suspension and termination for abusive conduct consistent with these proposed revisions to § 155.220(j)(2)(G).

In accordance with § 155.305(f), a consumer may only be eligible for APTC if they are an applicable taxpayer, in accordance with 26 CFR 1.36B-2(b), which requires a taxpayer to have household income that is at least 100 percent but not more than 400 percent of the Federal Poverty Level for the taxpayer's family size for the taxable year. Further, in accordance 42 CFR 435.603(h), Medicaid financial eligibility for applicants, and other individuals not receiving Medicaid benefits at the point at which eligibility for Medicaid is being determined, must be based on current monthly household income and family size.

Our investigations have shown that some agents, brokers, or web-brokers are entering incorrect tax household compositions on Exchange eligibility applications. Agents, brokers, or web-brokers often fail to ask consumers about members of their household, as required in the eligibility application. For example, we have observed agents, brokers, and web-brokers who omit questions about marital status, spouse's name, spouse's health insurance coverage, and whether the applicant and their spouse are filing income tax returns jointly or separately. We have also seen instances where an agent, broker, or web-broker asks consumers about their household composition but does not include all household members on the Exchange eligibility application. Agents, brokers, and web-brokers are required to include all household members even if those household members are not applying for coverage. Our investigations have also uncovered situations where some Exchange eligibility applications that included an agent, broker, or web-broker's NPN included fictitious household members.

Omitting any part of the household composition information on the eligibility application is likely to cause harm to the affected consumer and therefore constitutes abusive conduct. For example, the consumer may be harmed financially, as APTC is an advanced payment based on projected tax household income and composition. If the consumer's actual household composition differs from the household composition on the eligibility application, the consumer may be required to repay any overpayment of APTC unexpectedly. Moreover, this practice causes harm to the Exchange as a result of the outflow of funds to pay APTC for ineligible

consumers. The submission of inaccurate household composition information can also harm a consumer by resulting in denial of a consumer's eligibility for Medicaid, CHIP, APTC, or CSRs. Thus, we propose that agents, brokers, and web-brokers must accurately enter information provided and confirmed by the consumer pertaining to all tax household members, and that failing to do so may result in suspension and termination for abusive conduct consistent with these proposed revisions to § 155.220(g)(5).

(6) Inaccurate Addresses

We propose in 45 CFR 155.220(j)(2)(ii)(I) that an agent, broker, or web-broker must accurately enter information provided and confirmed by the consumer regarding residence address in accordance with 45 CFR 155.305(a)(3).

Under § 155.305(a)(3), for a consumer who is age 21 and over, the service area of the Exchange of the individual generally must be the service area of the Exchange in which the individual is living and intends to reside or otherwise has entered with a job commitment or is seeking employment. The Exchange uses the same standard for assessing or determining residency for purpose of Medicaid eligibility, consistent with 42 CFR 435.403(h)(1). Per 45 CFR 155.305(d), the Exchange also uses the same standards for assessing or determining residency for purpose of CHIP eligibility outlined in 42 CFR 457.320(e).

Our prior investigations have shown that some Exchange eligibility applications submitted by agents, brokers, or web-brokers include inaccurate residency information, particularly inaccurate addresses. For example, some agents, brokers, and web-brokers enrolling consumers at addresses where the consumer has never resided (for example, in a State in which they have never resided) or no longer resides. Inaccurate address information is likely to cause harm both to the consumer and the Exchange by interfering with the ability of the Exchange and its QHP issuers to communicate properly with the consumer about their health insurance coverage, upcoming Open Enrollment, or issues with their eligibility determinations. In our investigations, we have also observed the use of inaccurate residential addresses as a means of

keeping individuals unaware that their personal information has been used to create a QHP enrollment for which an agent, broker, or web-broker is collecting commission payments. Thus, we propose that agents, brokers, and web-brokers must accurately enter information provided and confirmed by the consumer regarding residence address in accordance with 45 CFR 155.305(a)(3), and that failure to do so may result in suspension and termination for abusive conduct in accordance with these proposed revisions to § 155.220(g)(5).

(7) Deceased Consumers

We propose in 45 CFR 155.220(j)(2)(ii)(F) that an agent, broker, or web-broker must submit application and enrollment data only for consumers who are not deceased at the time of enrollment, and that failure to do so may result in suspension and termination for abusive conduct consistent with these proposed revisions to § 155.220(j)(2)(G).

Our prior investigative efforts and data analytics have also shown that some Exchange eligibility applications submitted by agents, brokers, or web-brokers are for consumers who were deceased at the time of enrollment. In accordance with § 155.220(j)(2)(ii), agents, brokers, and web-brokers must document that the eligibility application information has been reviewed and confirmed to be accurate by the consumer, or the consumer's authorized representative designated in compliance with § 155.227, prior to the submission of the eligibility application. A deceased consumer cannot review and confirm the accuracy of their eligibility application information. We believe existing § 155.220(j)(2)(ii) makes clear that an agent, broker, or web-broker does not have consent to enroll deceased consumers. However, to increase transparency, we are proposing to add § 155.220(j)(2)(ii)(F) that would explicitly prohibit the enrollment of deceased consumers.

The enrollment of deceased consumers causes harm to Exchange operations in multiple ways. First, enrollment of deceased consumers creates administrative burden for the Exchange to recoup APTC payments to QHP issuers made on these improperly created policies. Second, the recoupment of those APTC payments results in unexpected and unpredictable cash outflows

for the QHP issuers who sell insurance on the Exchange. Third, the creation of these policies fundamentally undermines the integrity and reliability of the Exchange as a market, where transactions ought to be reliable and trustworthy when information is passed from consumer to Exchange to QHP issuer.

5. Extension of the Rebuttal Period

Under the existing framework in § 155.220(g)(5), in circumstances where we suspend an agent, broker, or web-broker's Exchange agreement(s), the agent, broker, or web-broker may submit evidence in a form and manner specified by CMS to rebut the allegation(s) during the 90-day period following the suspension. We propose in revised § 155.220(g)(5)(ii)(B) that if the agent, broker, or web-broker submits such evidence within 30 days of the suspension, CMS will review the evidence and make a determination on whether to lift the suspension within 90 calendar days of the suspension. This would provide CMS at least 60 calendar days for review of evidence submitted by an agent, broker, or web-broker as such evidence must be submitted within the first 30 days of the 90-day suspension period.

Based on our experience with prior Exchange oversight activities, we believe that extending CMS' review time from the current 45 calendar days to at least 60 calendar days is appropriate to allow CMS more time to review the submitted evidence and make an informed decision about whether such evidence persuades us to lift the suspension. These additional days are needed as the review process can involve parsing complex technical information and data, revisiting consumer complaints, and reaching out to consumers individually. While this proposal adds days to the review process, this minimal additional burden to agents, brokers, and web-brokers strikes the appropriate balance of protecting the FFEs, SBE-FPs, and their consumers from abusive conduct and quickly reviewing and making rebuttal determinations for agents, brokers, and web-brokers. This proposed review period also aligns with the 60-calendar day review period CMS has to review an agent, broker, or web-broker's reconsideration request

under the revised 155.220(g)(5)(iii) and (h), which would make this process easier for CMS to administrate and regulated entities to follow.

We seek comment on these proposals.

E. Restriction on Access to the FFEs and SBE-FPs and Exchange Data from Outside the United States

We propose to add 45 CFR 155.220(j)(2)(ix) to codify existing requirements in the Exchange agreements described in § 155.220(d) that agents, brokers, and web-brokers enter into with the FFEs and SBE-FPs that prohibit agents, brokers, and web-brokers from remotely connecting, attempting to remotely connect, or transmitting data to the FFEs and SBE-FPs and systems that transmit data to the FFEs and SBE-FPs, from outside the United States or its territories, embassies, or military installations (referred to hereafter as the "United States" for brevity).[181] The prohibitions in the existing agreements include a prohibition against using a Virtual Private Network (VPN) or other similar technology that routes Exchange system traffic through a server, network, or other point located outside the United States, regardless of whether the agent, broker, or web-broker is physically located inside the United States.

Data, including consumer PII, once transmitted outside the United States, may not be recoverable because it becomes subject to a foreign jurisdiction or otherwise falls outside of CMS' enforcement authority. This means CMS loses the ability to ensure deletion, recovery, or continued protection of that data once it is transmitted outside the United States. Additionally, access from outside the United States may occur through networks, devices, or infrastructure that are not subject to the same cybersecurity standards and legal protections applicable to domestic systems, increasing the risk of data breaches and other cyberattacks. Foreign access also

[181] *See* the PY 2027, "Agent Broker General Agreement for Individual Market Federally-Facilitated Exchanges and State-Based Exchanges on the Federal Platform," (Section IV, sub-section m), "Privacy and Security Agreement Between Agent or Broker and the Centers for Medicare & Medicaid Services for Individual Market Federally-Facilitated Exchanges and State-Based Exchanges on the Federal Platform," (Section V, sub-section l), and "Agreement Between Web-Broker and The Centers for Medicare & Medicaid Services for the Federally-Facilitated Exchanges and State-Based Exchanges on the Federal Platform," (Section X.m.).

significantly complicates CMS' ability to monitor, audit, and enforce compliance with the data security requirements applicable to agents, brokers, and web-brokers assisting consumers with enrollments through the FFEs and SBE-FPs because the relevant systems, devices, records, personnel, or data may be located outside United States jurisdiction or otherwise beyond CMS' direct oversight and enforcement authority. For example, CMS has encountered situations in which an agent, broker, or web-broker routed outbound emails containing consumer PII through third-party email servers located outside the United States. In one such case, CMS determined that consumer PII was accessible to overseas technical teams through shared IT infrastructure, and that the entity's security posture was insufficient to prevent unauthorized foreign access to Exchange Systems. Data breaches and cyber-attacks of consumer PII transmitted outside the United States could result in consumer information getting into the hands of agents, brokers, or web-brokers that are looking to gain commissions through unauthorized enrollments or plan changes or to sell consumer information to other agents, brokers, or web-brokers looking to do so. Thus, these risks may result in significant consumer harm, including interruptions or loss of health coverage, and improper determinations or payments of APTCs or CSRs that may create financial consequences for consumers and taxpayers.

Existing Exchange agreements already prohibit remote connections to the FFEs and SBE-FPs, and systems connected to the FFEs and SBE-FPs from outside the United States, including through the use of technologies such as VPNs.[182] The prohibition on access routed through technologies such as VPNs also captures situations where an agent or broker may be located in the United States, when accessing Exchange Systems but Exchange system traffic is routed outside the United States, such that consumer PII becomes accessible to foreign actors or subject to foreign jurisdiction.

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[182] *Id.*

We are proposing to codify a standard that would require agents, brokers, and web-brokers to implement and maintain reasonable administrative, technical, and contractual safeguards. These safeguards would be designed to ensure that access and attempted access to the FFEs and SBE-FPs, systems that support the FFEs and SBE-FPs, and PII obtained through the FFEs and SBE-FPs by the agent, broker, or web-broker and all employees, contractors, subcontractors, and other downstream entities acting on their behalf occurs only from locations within the United States. For the purposes of this proposal, systems that support the FFEs and SBE-FPs, collectively referred to as "Exchange Systems," would include, but not be limited to systems used for agent and broker training, registration, and certification; CMS identity and access management; and eligibility and enrollment functions.

Consistent with the existing prohibition in the Exchange Agreements, the proposal further provides that such reasonable safeguards must include safeguards to ensure that VPN**s** or other similar technologies do not route Exchange system traffic through a server, network, or other point located outside the United States regardless of whether the agent, broker, or web-broker is physically located inside the United States at the time of access, and regardless of whether the technology causes the access to appear to originate from a location inside the United States. Therefore, agents, brokers, and web-brokers would have to implement and maintain reasonable safeguards to ensure that their network architecture and any third-party services they use do not result in Exchange system traffic being routed, stored, or processed on foreign infrastructure.

In addition, we propose that CMS would not find an agent, broker, or web-broker noncompliant with the proposed requirements due to unauthorized activity resulting from compromised credentials or inadvertent network activity that the agent, broker, or web-broker could not reasonably have known about or prevented through reasonable safeguards. Agents, brokers, and web-brokers would be required to implement reasonable safeguards, such as network monitoring, access controls, and contractual restrictions on third-party service providers, to prevent prohibited access, including inadvertent routing. CMS would not find an agent,

broker, or web-broker noncompliant with the proposed standard if they implemented such safeguards and a prohibited connection nonetheless occurs that the agent, broker, or web-broker could not reasonably have known about or prevented through reasonable safeguards.

We believe it is appropriate that agents, brokers, and web-brokers implement and maintain reasonable safeguards to prevent prohibited access by all employees, contractors, subcontractors, and other downstream entities acting on their behalf because it would help ensure that the proposed requirement cannot be circumvented by delegating Exchange-related functions to another individual or entity. When CMS determines through its existing monitoring, audit, or enforcement activities that an employee, contractor, subcontractor, or downstream entity accessed the FFEs and SBE-FPs, Exchange Systems, or PII obtained through the FFEs and SBE-FPs from outside the United States on behalf of an agent, broker, or web-broker, CMS would treat such conduct as noncompliance by the agent, broker, or web-broker and pursue appropriate enforcement against the agent, broker, or web-broker under the applicable regulations. However, CMS would not find an agent, broker, or web-broker noncompliant with the proposed prohibition if an agent, broker, or web-broker can demonstrate they had implemented reasonable safeguards related to their contractor, subcontractor, or downstream entity's access to the FFEs and SBE-FPs, Exchange Systems, or PII obtained through the FFEs and SBE-FPs and prohibited access or attempted access nonetheless occurs without their knowledge or authorization. Reasonable administrative, technical, contractual, and oversight measures may include but are not limited to the following:

- Contractual measures: Including express prohibitions on foreign access to Exchange Systems in contracts with employees, contractors, subcontractors, and downstream entities; requiring such individuals or entities to attest to compliance with the foreign access prohibition; and including audit rights allowing the agent, broker, or web-broker to verify compliance by such individuals or entities.

- Technical measures: Implementing network access controls that restrict connections to Exchange Systems to domestic IP addresses; deploying monitoring tools that detect and alert on access attempts from foreign locations or through foreign infrastructure; requiring multi-factor authentication for all Exchange System access; and configuring systems to block VPN or proxy connections that route Exchange traffic through foreign servers.

- Oversight measures: Conducting periodic reviews of access logs to identify unauthorized or suspicious connection attempts; requiring employees, contractors, subcontractors, and downstream entities to promptly report any known or suspected foreign access incidents; and maintaining documentation of compliance oversight activities sufficient to demonstrate that reasonable controls were in place.

CMS recognizes that what constitutes reasonable controls will depend on the facts and circumstances of each case, including the nature of the downstream relationship and the type of Exchange System access involved. CMS expects all regulated parties to take meaningful steps commensurate with their resources and the nature of their downstream relationships.

Codifying this requirement would protect the FFEs and SBE-FPs against the risk associated with access to Exchange Systems from outside of the United States and ensure agents, brokers, and web-brokers are notified that CMS may monitor, audit, and conduct enforcement activities related to access to Exchange Systems from outside of the United States in accordance 45 CFR 155.220(j)(2)(ix) and 155.220(c)(5), and consistent with applicable law. In addition, codification of these requirements would ensure that CMS is empowered to take appropriate enforcement actions available under 155.220(g)(1) through (5), (k)(1), and (k)(3) against agents, brokers, and web-brokers participating in the FFEs and SBE-FPs who violate this provision, protect consumer PII, and remove noncompliant agents, brokers, and web-brokers from the FFEs and SBE-FPs.

We seek comment on this proposal.

VII. Clarifying Existing Requirement and Adding a New Unsolicited Beneficiary Contact Prohibition

CMS proposes to add a new supplier standard under 42 CFR 424.57(c)(31) to prohibit unsolicited beneficiary contact by DMEPOS suppliers and their agents when supplying a Medicare-covered item (as that term is defined in 42 CFR 424.57(a)) using direct messages from social media platforms, email messages without opt-out features, and door-to-door in-person solicitation. As in 42 CFR 424.57(c)(11), if (1) the beneficiary has provided written permission to the supplier to contact the beneficiary by direct social media message, email message without opt-out features, or door-to-door in-person solicitation concerning the furnishing of a Medicare-covered item that is to be rented or purchased; (2) the supplier has furnished a Medicare-covered item to the beneficiary and is contacting the beneficiary to coordinate delivery; or (3) the supplier has previously furnished a covered item to the beneficiary in the 15-month period prior to the date of contact, then the communication would be permitted. This proposal is intended to prevent DMEPOS suppliers from targeting Medicare beneficiaries with unsolicited direct contact, including high-pressure marketing tactics or deceptive lead generation that allow DMEPOS suppliers to bill Medicare for medically unnecessary or unneeded items, or items that are never supplied.[183]

Additionally, CMS proposes to clarify the existing 42 CFR 424.57(c)(11) prohibition against unsolicited beneficiary contact by DMEPOS suppliers to make explicit the inclusion of third-party entities acting as the agents of DMEPOS suppliers (agents). CMS also proposes to clarify this provision by clarifying that contact by telephone refers to a telephone call or message, including text messages. If finalized, these clarifications to 42 CFR 424.57(c)(11) and the addition of 42 CFR 424.57(c)(31) would become effective 60 days after the publication of the final rule.

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[183] Section 1834(a)(17) of the Act prohibits DMEPOS suppliers from soliciting Medicare beneficiaries by telephone, unless the beneficiary has given prior written consent or the supplier has an existing relationship with the beneficiary.

A. Current DMEPOS Supplier Standards

Section 1834(j)(1)(A) of the Act states that no payment may be made for items furnished by a supplier of medical equipment and supplies unless such supplier obtains (and renews at such intervals as the Secretary may require) a supplier number. To obtain a supplier billing number, a supplier must comply with certain supplier standards as identified by the Secretary. Section 1834(j)(1)(B) of the Act gives the Secretary the authority to establish additional supplier standards. Consistent with the statutory authority described in sections 1834(j)(1)(A) and (B) of the Act, CMS established DMEPOS supplier standards set forth in 42 CFR 424.57(c), and may clarify and revise the DMEPOS supplier standards as needed to ensure the efficient administration of the Medicare program.[184]

Current 42 CFR 424.57(c)(11) requires that DMEPOS suppliers, when supplying a Medicare-covered item, agree not to contact a beneficiary by telephone unless the beneficiary has provided written permission to the supplier to contact the beneficiary by telephone concerning the furnishing of a Medicare-covered item that is to be rented or purchased, the supplier has furnished a Medicare-covered item to the beneficiary and is contacting the beneficiary to coordinate delivery, or the supplier has previously furnished a covered item to the beneficiary in the 15-month period prior to the date of contact. The existing requirement is one of the conditions that DMEPOS suppliers must meet to be eligible to receive payment for a Medicare-covered item and to participate in the program. Existing regulations at 42 CFR 424.57(e)(1) state that a DMEPOS supplier's failure to meet supplier standards may result in revocation of the supplier's Medicare billing privileges. If CMS or a DMEPOS supplier-accrediting body has evidence that a DMEPOS supplier has made prohibited contact with Medicare beneficiaries in violation of the provisions found in 42 CFR 424.57(c)(11), CMS may revoke that supplier's billing privileges. CMS also will determine whether submitted claims

[184] Section 1871(a)(1) of the Act provides the Secretary the right to prescribe regulations as may be necessary to carry out the administration of the Medicare program.

related to such contact are for unnecessary supplies, and may refer the supplier to law enforcement should it suspect potential fraud.

CMS briefly expanded the scope of the prohibition against unsolicited direct contact of Medicare beneficiaries by DMEPOS suppliers. In 2010, CMS published a final rule intended to strengthen the Medicare DMEPOS supplier standards specified in 42 CFR 424.57 to enhance the program integrity protections for Medicare FFS DMEPOS.[185] In the 2010 rule, CMS finalized a definition of "direct solicitation" that expanded the existing prohibition on unsolicited direct contact of Medicare beneficiaries via telephone, with certain exceptions.[186] During that rulemaking, several commenters expressed concerns that the expanded prohibition restricted commercial speech.[187] Following publication of the 2010 final rule, CMS subsequently determined that implementing the expanded prohibition was unfeasible because the definition of "direct solicitation" it had finalized was overly broad, warranting further evaluation.

Accordingly, in a 2011 proposed rule, CMS proposed to remove the definition of "direct solicitation" and restore the supplier standard that existed prior to the 2010 rule.[188] CMS finalized that proposal in 2012, reverting to the prior standard and stating that the language in the 2010 final rule would have prohibited some types of marketing activity beyond what CMS intended to prohibit.[189]

B. Pervasiveness of Medicare DMEPOS Fraud, Waste, and Abuse

DMEPOS fraud, waste, and abuse in the Medicare program has been a serious problem for many years, placing billions of taxpayer dollars at risk and potentially resulting in patient

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[185] Ctrs. for Medicare & Medicaid Servs., Medicare Program; Establishing Additional Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Enrollment Safeguards, 75 FR 52629 (August 27, 2010), *available at* federalregister.gov.
[186] 75 FR 52639.
[187] 75 FR 52638.
[188] 76 FR 18474.
[189] CMS, Medicare Program; Revisions to the Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Safeguards, 77 FR 14990 (March 14, 2012), *available at* federalregister.gov.

harm when beneficiaries use medically unnecessary or substandard items.[190, 191] CMS' role in overseeing the Medicare program is to ensure that payments are made correctly and that fraud, waste, and abuse is stemmed because failure to do so endangers the Trust Funds and may result in beneficiary harm. Consequently, CMS rigorously scrutinizes DMEPOS suppliers upon enrolling, and to maintain enrollment, in Medicare.[192] Despite these safeguards, fraudulent billing for Medicare DMEPOS continues to be a major concern, and new schemes continue to emerge.[193]

In fact, in 2026, CMS announced a nationwide temporary enrollment moratorium on newly enrolling Medicare DMEPOS medical supply companies based on evidence that the supplier category presented significant program integrity concerns, including a history of fraudulent billing and other abusive practices. CMS determined that temporarily restricting new enrollments was necessary to protect Medicare while preserving beneficiary access through the substantial number of existing enrolled suppliers. A nationwide approach was taken because it was clear to us that DMEPOS fraud, waste, and abuse was not restricted to certain types of items or particular areas of the country. Rather, it was widespread across DMEPOS types and geographic areas.

Additionally, in March 2025, CMS launched the Fraud Defense Operations Center (FDOC), also referred to as the Fraud War Room, a cross-functional unit combining data analysts, investigators, health policy experts, legal advisors, and law enforcement personnel to

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[190] *See* CMS, Medicare and Medicaid Programs; Calendar Year 2026 Home Health Prospective Payment System (HH PPS) Rate Update; Requirements for the HH Quality Reporting Program and the HH Value-Based Purchasing Expanded Model; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program Updates; DMEPOS Accreditation Requirements; Provider Enrollment; and Other Medicare and Medicaid Policies, 90 FR 29108 (proposed July 2, 2025), *available at* federalregister.gov; CMS, Medicare, Medicaid, and Children's Health Insurance Programs: Announcement of Nationwide Temporary Moratoria on Enrollment of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier Medical Supply Companies, 91 FR 9855 (February 27, 2026), *available at* federalregister.gov.

[191] The FY 2025 Medicare estimated improper payment amount for DMEPOS is $2.27 billion. Improper payments are payments that do not meet Medicare requirements or are made in incorrect amounts. *See* https://www.cms.gov/data-research/monitoring-programs/improper-payment-measurement-programs/comprehensive-error-rate-testing-cert

[192] 90 FR 29108. https://www.federalregister.gov/d/2025-12347/p-699

[193] *Id*.

identify and interdict fraudulent billing before payment is made. In its first year of operation (March 31, 2025 through March 31, 2026), the FDOC suspended payments to 138 suspect DMEPOS suppliers, and as of August 2026, was holding $1.9 billion through these payment suspensions.

In many fraud schemes, DMEPOS suppliers and their agents target Medicare beneficiaries with unsolicited direct contacts and use high-pressure marketing tactics or deceptive lead generation to obtain information and consent to enable the DMEPOS supplier to bill Medicare for medically unnecessary or unneeded items, or items that are never supplied at all. This unsolicited direct contact may include emails, text messages, direct messages on social media, and door-to-door in person solicitation. Increasingly, these schemes involve third-party organizations, such as telemarketers or independent marketing firms. In some cases, unsolicited outreach to beneficiaries is used to offer free services, medical equipment, or gift cards in exchange for their Medicare number, which is then used to fraudulently bill Medicare.[194]

Advances in technology also allow bad actors to spoof the number that appears on a beneficiary's caller ID so that an incoming call appears to be from a trusted health care provider or government agency.[195] Scammers also target Medicare enrollees through text messages with offers of free services, medical equipment, or gift cards upon confirming their personal information and eligibility for specific Medicare services. Often, the enticement for the individual is that they are "qualified" for items "at no cost" or "free." Once the scammers obtain the enrollee's personal information, monthly billing to Medicare will begin for medically unnecessary supplies that may or may not actually be sent to the enrollee.[196] Accordingly, CMS has gone to great lengths to discourage beneficiaries from providing personal information such as Medicare or Social Security numbers, including a longstanding "Guard Your Card" campaign

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[194] https://oig.hhs.gov/fraud/consumer-alerts/consumer-alert-catheter-scam/; https://www.justice.gov/opa/pr/national-health-care-fraud-takedown-results-324-defendants-charged-connection-over-146

[195] https://www.fcc.gov/older-americans-and-medicare-scams

[196] https://www.oig.hhs.gov/fraud/consumer-alerts/consumer-alert-catheter-scam/

that offered such tips as "Don't share your Medicare Number or other personal information with anyone who contacts you by phone, email, or approaches you in person, unless you've given them permission in advance."[197]

As previously described, CMS published a Request for Information (RFI Related to Comprehensive Regulations To Uncover Suspicious Healthcare (CRUSH) on February 27, 2026.[198] This RFI requested stakeholder feedback on a number of potential regulatory and programmatic changes, including a possible change to the existing prohibition against unsolicited contact by telephone by DMEPOS suppliers.[199] CMS received multiple comments in response to the RFI that were generally supportive of efforts to curb abusive marketing and lead generation practices involving unsolicited beneficiary contact and specifically supported broadening the prohibition. Commenters described unsolicited telephone calls, texts, emails, and door-to-door solicitations, and noted concerns about third-party marketing firms and other entities acting on behalf of DMEPOS suppliers. Commenters also described agents approaching beneficiaries at their homes, unsolicited, and sometimes combined with emails using high pressure sales tactics to get approval for services, which the beneficiaries do not need or approve, yet claims were generated by the suppliers as though consent was provided. Several other commenters did express concern, however, about how further restrictions on solicitation may disrupt DMEPOS care coordination or patient education.

C. Proposed Revisions to Supplier Standards Pertaining to Beneficiary Solicitation

Despite the existing program integrity controls in place pertaining to beneficiary solicitation by DMEPOS suppliers, fraudulent billing for Medicare DMEPOS continues to be a major concern, and new schemes have emerged. A crucial element in many of these schemes is the targeted, unsolicited contact with beneficiaries by DMEPOS suppliers and their agents, who

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[197] https://www.medicare.gov/publications/10111-protecting-yourself-from-fraud.pdf

[198] Ctrs. for Medicare & Medicaid Servs.https://www.federalregister.gov/documents/2026/02/27/2026-03968/request-for-information-rfi-related-to-comprehensive-regulations-to-uncover-suspicious-healthcare, Request for Information (RFI) Related to Comprehensive Regulations to Uncover Suspicious Healthcare (CRUSH), 91 FR 9803 (proposed February 27, 2026), *available at* federalregister.gov.

[199] 91 FR 9806. https://www.federalregister.gov/d/2026-03968/p-78

use manipulative tactics to obtain personal information and consent. Accordingly, CMS has determined that a clarification to make explicit the prohibition on unsolicited beneficiary contact by DMEPOS suppliers (and third-party entities acting as their agents) when supplying a Medicare-covered item is needed to address these schemes. We believe that making explicit the supplier standards specified in 42 CFR 424.57(c)(11) and the addition of new supplier standard at 42 CFR 424.57(c)(31) would help to ensure that legitimate DMEPOS suppliers furnish items of DMEPOS to Medicare beneficiaries consistent with Medicare requirements.

Specifically, we are proposing to revise the supplier standard at 42 CFR 424.57(c)(11) to clarify that suppliers must agree that they and their agents shall not contact a beneficiary when supplying a Medicare-covered item by telephone call or message, including text messages unless one of the following applies: (i) the beneficiary has provided written permission to the supplier to contact the beneficiary by telephone concerning the furnishing of a Medicare-covered item that is to be rented or purchased; (ii) the supplier has furnished a Medicare-covered item to the beneficiary and is contacting the beneficiary to coordinate delivery; or (iii) the supplier has previously furnished a covered item to the beneficiary in the 15-month period prior to the date of contact. This clarification would be consistent with the Telephone Consumer Protection Act's[200] long-standing definition of "telephone solicitation" as the initiation of a telephone call or message for the purpose of encouraging purchases or rentals of property, goods, or services, but excludes such a call or message when express permission for contact has been granted or there is an established business relationship.

In accordance with our authority in section 1834(j)(1)(B) of the Act to establish additional supplier standards, we are also proposing to add a supplier standard at 42 CFR 424.57(c)(31) that would require that a supplier must agree that they and their agents shall not contact a beneficiary when supplying a Medicare-covered item using direct messages from social

[200] 47 USC 227(a)(4) (1991).

media platforms, email messages without opt-out provisions, and door-to-door in-person solicitation unless one of the following applies: (i) the individual has given written permission to the supplier to contact them concerning the furnishing of a Medicare-covered item that is to be rented or purchased; (ii) the supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item; or (iii) if the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier makes such contact.

We also propose to clarify that both 42 CFR 424.57(c)(11) and (31) apply to all DMEPOS suppliers, whether the DMEPOS supplier itself or another qualified party is furnishing the item. We believe such clarification is necessary in light of our observations that third-party organizations, such as telemarketers and independent marketing firms, are increasingly working with DMEPOS suppliers to engage in fraudulent schemes targeting Medicare. We note, however, that our proposed clarification that 42 CFR 424.57(c)(11) would apply to third-party agents and would not expand the existing prohibition. CMS and HHS-OIG have long interpreted the current version of 42 CFR 424.57(c)(11) as prohibiting DMEPOS suppliers from using agents or other third parties to make unsolicited telephone calls that improperly target consumers.[201]

CMS must take action to safeguard the Medicare program when bad actors exploit advances in technology and engage in coercive, high-pressure marketing tactics that result in the proliferation of fraudulent Medicare DMEPOS billing schemes. In doing so, however, CMS has continuously weighed the impact of additional contact limitations on both program integrity and DMEPOS suppliers' rights to engage in Constitutionally protected speech.

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[201] https://oig.hhs.gov/newsroom/news-releases-articles/hhs-oig-alerts-medicare-suppliers-beneficiaries-about-prohibited-telemarketing-calls/; HHS-OIG; Publication of OIG Updated Special Fraud Alert on Telemarketing by Durable Medical Equipment Suppliers, 75 FR 2105 (January 14, 2010); *available at* federalregister.gov.https://www.federalregister.gov/d/2010-562/p-11

We believe that this proposed rule avoids the overly broad language of previous efforts and, if finalized as proposed, would not prohibit otherwise permissible marketing activity. This proposal is appropriately limited in scope and focuses on targeted communication that has significantly contributed to fraudulent Medicare DMEPOS billing. The proposed changes are designed not to prevent DMEPOS suppliers from engaging in legitimate marketing communications, but, instead, to strengthen CMS program integrity efforts to safeguard the Medicare program by preventing DMEPOS suppliers from utilizing third-party entities to indirectly engage in unsolicited beneficiary contact in which DMEPOS suppliers themselves may not engage when supplying a Medicare-covered item.[202] Further, the proposed changes would add methods of communication, such as electronic direct messages from social media platforms, that have provided new ways for bad actors to target Medicare beneficiaries with aggressive and deceptive tactics that can lead to fraudulent Medicare billing and other abusive practices.

The proposed revisions to the supplier standards aim to address critical program integrity concerns but would have a limited impact on a DMEPOS supplier's ability to advertise products and services to the general public or Medicare beneficiaries generally, or to otherwise engage in legitimate marketing activities. Television commercials, which broadcast ads for products or services with clear disclosures (for example, pharmaceutical ads listing side effects), radio advertisements, and print advertisements in newspapers, magazines, or brochures are examples of legitimate marketing activities that these proposals would not limit. Likewise, generalized advertising on digital platforms is another example of a legitimate marketing activity.

In this proposed rule, CMS proposes to clarify the existing 42 CFR 424.57(c)(11) prohibition against unsolicited beneficiary contact by DMEPOS suppliers and add a new DMEPOS supplier standard under proposed 42 CFR 424.57(c)(31). We also propose to add specific severability

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[202] *See* HHS-OIG, Publication of OIG Special Fraud Alert on Telemarketing by Durable Medical Equipment Suppliers, 68 FR 10254 (March 4, 2003); *available at* federalregister.gov.

clauses at 42 CFR 424.57(c)(11)(ii) and (31)(ii). To the extent a court may enjoin one provision of this rule as finalized, CMS proposes that the other provisions should remain in effect, ensuring the continuity of the regulations. We propose that any provision of the requirements of this rule that is held to be invalid or unenforceable by its terms or as applied to any person or circumstance would be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding is one of utter invalidity or unenforceability, in which event we propose that the provision would be severable from the other provisions of this rulemaking and would not affect the remainder thereof or the application of the provision to persons not similarly situated or to dissimilar circumstances.

We propose that if any section, subsection, sentence, clause, phrase, word, provision, or application of this proposed rule as finalized shall be found to be invalid, illegal, unconstitutional, or unenforceable, that finding shall not affect or undermine the validity of any other section, subsection, sentence, clause, phrase, word, provision, or application which can be enforced without the use of the offending provision. We request comments from the public on severability, particularly which policies could be severable, if finalized, and how the other policies in a final rule would operate absent those particular provisions.

We seek comments on this proposed clarification and addition to the prohibition on unsolicited beneficiary contact by DMEPOS suppliers wishing to receive payment from Medicare.

VIII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501-3520, we are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain confirmed or potential information collection requirements (ICRs). Comments, if received, will be responded to within the subsequent final rule (CMS-6098-F, RIN 0938-AV97).

A. Wage Estimates

To derive average costs and savings, we used data from the U.S. Bureau of Labor Statistics' (BLS') May 2025 National Occupational Employment and Wage Statistics for all wage estimates (*https://www.bls.gov/oes/tables.htm*). In this regard, Table C-A1 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs[203] (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE C-A1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

[203] *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

Occupation Title	Occupational Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Business Operations Specialists	13-1000	43.76	43.76	87.52
Business Operations Specialists, All Other	13-1199	45.18	45.81	90.36
Claims Adjusters, Examiners, and Investigators	13-1031	38.69	38.69	77.38
Eligibility Interviewers, Government Programs	43-4061	26.97	26.97	53.94
Computer Systems Analysts	15-1211	55.10	55.10	110.20
General and Operations Managers	11-1021	64.87	64.87	129.74
Human Resources Managers	11-3121	78.96	78.96	157.92
Management Analysts	13-1111	54.71	54.71	109.42

For States and the private sector, the employee hourly wage estimates have been adjusted upwards by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

To estimate the financial burden on States, it was important to consider the Federal government's contribution to the cost of administering the Medicaid and CHIP programs. The Medicaid FMAP that is established for each State is based on the per capita income in the State as compared to the national average. Medicaid FMAPs range from a minimum of 50 percent in States with higher per capita incomes to a maximum of 83 percent in States with lower per capita incomes, but exceptions to the regular FMAP rate exist for certain States, situations, populations, providers, and services. For Medicaid, all States generally receive a 50 percent FMAP for administration. States also receive higher Federal matching rates for certain systems improvements, redesign, or operations, including a 90 percent match rate for the design, development, and enhancement of Medicaid information technology (IT) systems. We have estimated that States would contribute 10 percent of applicable Medicaid IT costs. For CHIP, Congress created an "enhanced" Federal matching rate for CHIP that is generally about 15 percentage points higher than the Medicaid rate, averaging 71 percent nationally. To determine the Federal contribution to the costs of administering the Medicaid and CHIP programs for purposes of estimating State burden with respect to the collections of information, we elected to

use the higher-end estimate that the States would contribute 50 percent of the costs. This assumption represents the upper bound of potential State burden, recognizing that the actual share is often lower once enhanced Federal match rates are applied.

B. Proposed Information Collection Requirements and Burden

This section details the information collection requirements (ICRs) and burden related to Enhancing Medicaid program integrity: deregulation of the MEQC program, Medicaid and CHIP beneficiary eligibility audits, Medicaid and CHIP beneficiary eligibility-related disallowances, PERM CAPs, Program Integrity CAPs, Medicaid fee-for-service overpayment reporting (60-day rule), Medicaid managed care oversight policies, enhanced electronic visit verification (EVV) requirements, and Medicaid and CHIP provider enrollment.

1. Medicaid and CHIP Program Integrity

a. ICRs Regarding Deregulation of the MEQC Program (§§ 431.800 through 431.820)

The MEQC Program is currently approved under OMB control number: 0938-0147 (Expiration date: 08/31/2029). This rule proposes to deregulate the MEQC program. We do not believe that the proposed changes would impose any new or revised collection of information requirements or burden, including those associated with the creation or revision of State plan or other State-owned policy documents. The proposed change would have no impact on any collection of information requirements including that of collecting information, reporting information, disclosing information, and/or recordkeeping. As a result, the proposed deregulation of the MEQC program would not be subject to the requirements of the PRA. The collection of information will be formally discontinued once the 3-year phaseout is complete. If the proposed regulation becomes effective, once the 3-year phaseout is complete at the end of 2029, the current COI cost of $22,020,936 associated with information requirements including that of collecting information, reporting information, disclosing information, and recordkeeping, will be discontinued, producing an ongoing annual State cost savings of $11,010,468 ($22.020,936÷2) starting in the year 2030, which is the State share amount of $22,020,936.

This will generate then an ongoing annual Federal cost savings/transfer to the Federal government of $11,010,468 starting in 2030 ($22.020,936÷2), which represents the 50 percent Federal administrative match amount that the Federal government would have paid but for the deregulation of the MEQC program.

b. ICRs Regarding PERM CAPs (§§ 431.992(a), (b)(3)(ii)(E), (b)(3)(ii)(F), (c), and (e) and 431.1010(b)(2)(ii))

The following proposed changes will be submitted to OMB for review under control number 0938-1012 (Expiration date: November 30, 2027).

Ensuring that States are taking necessary steps as part of their PERM CAPs is vital to CMS and States being able to reduce improper payments in future years. While we provide guidance to States throughout the entire PERM CAP process, we currently have limited enforcement authority to ensure that States comply with all PERM CAP requirements and effectively attempt to reduce or prevent future PERM errors.

Under new § 431.992(c), this proposed rule would provide us with explicit authority to approve (with required revisions, as needed) or disapprove a State's PERM CAP. This would allow us to ensure that States submit high-quality, effective, and robust PERM CAPs that would reduce future errors, while also allowing us to make more effective "good faith effort" determinations.

Currently, as part of the PERM CAP development process, we review the CAP developed by the State to ensure that it includes all requirements outlined in § 431.992, including the identification of root causes of improper payments, how the State plans to avoid repeat errors, how the State will monitor CAP implementation, and evaluate the effectiveness of the corrective actions. In instances in which this information is missing or deemed insufficient by us, a request for additional information is issued to the State, and the State is expected to make the updates until the information in the PERM CAP is deemed by CMS to meet regulatory requirements. This process would largely be unchanged under these new regulations, as this

proposal would simply provide CMS with the authority to approve or disapprove a State's PERM CAP. We do not believe that this proposal to provide CMS with explicit authority to approve or disapprove a State's PERM CAP would lead to an increased workload or costs on States. The request for additional information is exempt from the requirements of the PRA since each request would be non-standardized across the States.

We are also proposing to amend § 431.992(a) to require States to submit a combined PERM CAP that addresses both Medicaid and CHIP PERM errors and deficiencies, as applicable. This provision proposes combining the Medicaid and CHIP CAPs, which would eliminate the need for States to duplicate responses on both CAPs, as the errors and corrective actions are generally similar across programs. This would reduce the time needed for States to meet PERM CAP regulatory requirements, as two separate CAPs would no longer be required. It is estimated that this change would reduce the burden on States' staff processing time by approximately 30 hours (from 60 to 30 hr) at $77.38/hr, which is the approximate time it takes claims adjusters, appraisers, examiners, and investigators to generate responses on two separate reports. In aggregate, we estimate an annual burden reduction of minus 510 hours (17 States x 30 hr) and minus $39,464 (-510 hr x $77.38/hr). Accounting for the 50 percent Federal administrative match, the total State savings is adjusted to minus $19,732 (-$39,464 x 0.50).

We are also proposing to amend § 431.992(e) to require States with a Medicaid and/or CHIP eligibility improper payment rate exceeding the allowable threshold of 3 percent for consecutive Payment Error Rate Measurement (PERM) years to submit corrective action plan implementation updates to us every 6 months (twice per year) as applicable. This provision proposes to reduce the frequency of the required eligibility updates from every other month (6 times per year) to allow States' additional time to evaluate corrective actions and provide higher quality, more comprehensive status updates, providing us with clearer insights into the States' progress and challenges.

It is estimated that this change would reduce the burden on States' staff processing time

by approximately 12 hours at $77.38/hr, which is the approximate time it takes claims adjusters, appraisers, examiners, and investigators to respond to eligibility updates 4 times per year. In aggregate, we estimate an annual burden reduction of minus 204 hours (17 States x 12 hr) and minus $15,786 (-204 hr x $77.38/hr). Accounting for the 50 percent Federal administrative match, the total State savings is adjusted to minus $7,893 (-$15,786 x 0.50). We summarize the proposed burden in Table C-A2 and compare the currently approved burden with the proposed burden in Table C-A3.

TABLE C-A2: SUMMARY OF PROPOSED BURDEN ASSOCIATED WITH PERM CAP REQUIREMENTS

Requirement	No. of Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Cost ($)	Federal Cost ($)
Submission of Combined Medicaid and CHIP PERM CAP (§ 431.992(a))	17 States	17	Annual	30	510	77.38	39,464	19,732	19,732
Submission of Eligibility Updates (§ 431.992(e))	17 States	34	Semiannual	3	102	77.38	7,893	3,946	3,946
TOTAL	17 States	51	Varies	-42	612	77.38	47,357	23,678	23,678

TABLE C-A3: COMPARISON OF STATE ADMINISTRATIVE COSTS AND SAVINGS FROM AMENDING 431.992 ASSOCIATED WITH PERM CAP REQUIREMENTS

Requirement	Measure	Current Annual Cost	Proposed Annual Cost	Annual Savings
Submission of Combined Medicaid and CHIP PERM CAP (§ 431.992(a))	Annual Responses	34	17	-17
	Annual Burden (hr)	1,020	510	-510
	State Share Cost ($)	39,464	19,732	-19,732
	Federal Cost/Transfer ($)	39,464	19,732	-19,732
	Total Cost ($)	78,928	39,464	39,464
Submission of Eligibility Updates (§ 431.992(e))	Annual Responses	102	34	-68
	Annual Burden (hr)	306	102	-204
	State Share Cost ($)	11,839	3,946	-7,893
	Federal Cost/Transfer ($)	11,839	3,946	-7,893
	Total Cost ($)	23,678	7,893	-15,785
TOTAL	**Annual Responses**	**136**	**51**	**-85**
	Annual Burden (hr)	**1,326**	**612**	**-714**
	State Share Amount ($)	**51,303**	**23,678**	**-27,626**
	Federal Cost/Transfer ($)	**51,303**	**23,678**	**-27,626**
	Total Cost ($)	**102,606**	**47,357**	**-55,249**

c. ICRs Regarding Medicaid and CHIP Managed Care Oversight Policies (§§ 438.3(c)(2) and 438.608(a)(3))

This rule proposes to clarify that managed care plans may not retain capitation payments for enrollees who have died or have moved out of State and also defines "prompt" reporting of

beneficiary changes. We do not believe that the proposed changes would impose any new or revised collection of information requirements or burden including those associated with the creation or revision of State plans or other State-owned policy documents. As a result, the proposed Medicaid managed care oversight policies would not be subject to the requirements of the PRA. CHIP is incorporated via 42 CFR 457.1201(c) and 457.1285.

d. ICRs Regarding Revisions to § 455.17 Reporting Requirements

This section discusses the ICR burden associated with our proposed revisions to § 455.17, which would modernize Medicaid fraud and abuse reporting requirements for State Medicaid agencies. This section should be read together with section VIII.B.2. of this proposed rule, "National Provider Identifier Requirements for Medicaid Providers," which addresses the separate burden associated with States collecting and maintaining NPIs generally; this section addresses only the burden of reporting the NPI as one of several data elements under § 455.17(b) once it is on file.

Table C-A4 lists the Bureau of Labor Statistics (BLS) hourly wage estimate(s) (see https://data.bls.gov/oes/#/area/0000000/2025) for the occupational category used in this section.

TABLE C-A4: MAY 2025 BLS NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
General and Operations Managers	11-1021	$64.87	64.87	$129.74

Under existing § 455.17(a), States are required to report to CMS the number of fraud and abuse complaints that warranted a full investigation. Under existing § 455.17(b), for cases of suspected provider fraud and abuse that warranted a full investigation, States are required to report six data elements, as described in section III. Medicaid and CHIP Program Integrity Proposals of this proposed rule.

We propose to amend § 455.17(b) to require States to report the following additional data elements for cases of suspected provider fraud and abuse that warranted a full investigation: (1) the provider's National Provider Identifier (NPI) or Medicaid provider identification number, if the provider is ineligible to receive an NPI; (2) the provider's Employer Identification Number or Taxpayer Identification Number (EIN/TIN); (3) the State in which the investigation is being conducted; (4) the investigation status; (5) the type of service involved; (6) the payor; (7) the relevant claim dates; (8) the estimated overpayment amount and, where available, the final overpayment amount; and (9) the approximate time period covered by the investigation. We also propose to replace the existing paragraphs (b)(1) through (6) with expanded requirements enumerated as paragraphs (b)(1) through (15). This will expand the reporting options for disposition of cases to include administrative actions taken by the State Medicaid agency, in addition to the existing requirement to report actions taken by law enforcement.

The ICR burden associated with this provision is limited to States collecting, compiling, and reporting these data elements for each qualifying case. There was a previously approved information collection for § 455.17, OMB Control No. 0938-0076 originally approved in 1978 and last approved by OMB in 1983. That control number expired in 1986. Following that expiration, CMS did not collect the information from States under § 455.17. Burden associated with this collection is associated with OMB control number 0938-0076; however, CMS is seeking to reinstate the collection. CMS will not begin collecting information related to these requirements until OMB approval is received.

We note that the provider's NPI (or Medicaid provider identification number, if the provider is ineligible to receive an NPI) is one of the nine additional data elements States would report under this proposal. Because this NPI/ID data element is reported as part of the same § 455.17(b) submission, for the same case, at the same time as the other eight additional data elements, we have not separately estimated its burden; the burden estimate in this section reflects the incremental time needed to compile and report all nine additional data elements together as a

single reporting action. This approach is consistent with our general practice of estimating ICR burden based on the reporting event (that is, the submission), rather than by individual data field within that submission.

Under § 455.17(b), States are required to report the specified data elements for each case of suspected provider fraud and abuse that warranted a full investigation. We estimate that on average each State refers approximately 30 such cases to its State Medicaid Fraud Control Units (MFCUs) on an annual basis, based on MFCU annual reports[204]. MFCU reports cover a 3-year period and on average States report an estimated 89.6 cases over a review period.

All 50 States, the District of Columbia, and the applicable territories (hereafter collectively "States") are subject to this reporting requirement. We estimate a range of 30 to 100 cases requiring the additional data elements per State annually. Specifically, we estimate 65 cases per State. [205] We estimate that it will take a State Medicaid agency official approximately 2.00 hours] to compile and report the additional data elements for each qualifying case. This estimate reflects the fact that much of this information (for example, claim dates, payor, and estimated overpayment amount) is likely already maintained by the State as part of its existing investigation and case management processes and would primarily require compilation and formatting for submission to CMS rather than new data collection. (65 cases per State annually x 52 States = 3,380 cases) (3,380 cases x 2.00 hours= 6,760 hours) (6,760 hours x $129.74= $877,042.40). The estimated annual cost is $877,042.40 with $438,521.20 as the State share, and $438,521.20 as the Federal transfer cost reflecting the 50 percent Federal administrative match.

To derive estimated cost, we used data from the U.S. Bureau of Labor Statistics' May 2025 Occupational Employment and Wages for the occupation, "General and Operations Managers" (Occupation Code 11-1021). This estimate includes the mean hourly wage ($64.87)

204 https://oig.hhs.gov/reports/all/?hhs-agency=MFCU&page=1

with benefits calculated at 100 percent ($64.87) totaling $129.74 per hour. We calculated this using the mean average of 65 cases annually.

We estimate that the data would be compiled and submitted to CMS by a State Medicaid program integrity official with an hourly wage equivalent to that of a GS-12, Step 5 Federal employee, or $ 86,659. (See [DCB.pdf salary table citation/link].) The figure is $173,318 with FBO.

Table C-A5 summarizes the estimated annual ICR burden for this provision.

TABLE C-A5: PROPOSED § 455.17(B) ICR BURDEN ESTIMATE

Provision/Requirement	OMB Number	Number of Respondents (States)	Number of Responses (Cases)	Burden per Response (Hours)	Total Annual Burden (Hours)	Hourly Wage (Includes FBO) ($)	Total Cost
Additional Data Elements Reported Under § 455.17(b), Including Provider NPI/ID	0938-0076	52	3,380	2.00	6,760	$129.74	$877,042.40
TOTALS		52	3,380	2.00	6,760	$129.74	$877,042.40

Note: The provider NPI/ID data element is captured within the single line item rather than as a separate row, consistent with the discussion in section VIII.B.1. of this proposed rule.

Per Table C-A5, we project an average annual ICR burden of 6,760 hours and $877,042.40 associated with the proposed revisions to § 455.17(b).

We note that proposed § 455.17(a) is not being substantively revised and therefore imposes a *de minimis* ICR burden. Burden will be accounted for under the newly proposed collection of information previously approved under OMB control number 0938-0076.

e. ICRs Regarding Medicaid and CHIP Provider Enrollment (§§ 455.2, 455.101, 455.104, 455.106, 455.416, 455.436, 455.450, and 455.460)

As discussed in section V. of this proposed rule, we are proposing a number of changes to our Medicaid and CHIP provider enrollment regulations in subparts B and E of part 455. The changes include, but are not limited to, the following:

- Adding and revising definitions.
- Clarifying certain types of provider enrollment data that Medicaid and CHIP providers must submit to States.
- Adding and revising reasons for which the State must deny or terminate a provider's

Medicaid enrollment.

- Revising provider enrollment application fee requirements.
- Making various technical revisions.

Under § 455.104, a disclosing entity must furnish to the State information regarding "any person (individual or corporation) with an ownership or control interest" in the disclosing entity. This information includes, for example:

- The aforementioned party's name, address, and tax identification number.
- Whether said party is related to another person with an ownership or control interest in the provider/disclosing entity.
- Identifying data about any managing employee of the disclosing entity.

We are proposing several revisions to these definitions and requirements. First, we propose to change the parenthetical "(individual or corporation)" in § 455.104 to "individual or organization." Second, we propose to add a definition of "managing organization" to § 455.101. The proposed revisions, in effect, would require the following:

- Providers that are individual practitioners or groups thereof to disclose the information outlined in § 455.104.
- Providers to disclose § 455.104 data about: (1) entities other than corporations; and (2) managing organizations.

We do not have available data upon which we can reasonably estimate the burden on providers for disclosing such information. This is largely because: (1) each State has its own provider enrollment process and means of collecting information (the burden of which could differ by State); (2) some States may already collect this data, meaning no additional burden from our proposal; and (3) each State receives different volumes of applications each year. We accordingly solicit comments from interested parties, especially the States, on this potential burden, specifically:

- For States that do not presently collect this information, the burden that the State

believes the provider would incur in reporting it.

- The burden that providers believe they would incur in collecting and reporting this data.

We also request data from the States regarding other potential information collection burdens that could arise from our proposed provider enrollment provisions. These could include, for instance, the State's: (1) revision of enrollment applications, internal procedures, and public guidance documents; and (2) processing of additional enrollment data.

For the foregoing requests for data concerning any enrollment information collection burden, we would appreciate statistics and burden calculations from interested parties that could help us prepare a reasonable burden assessment.

f. ICRs Regarding Medicaid Payment Suspensions Updates (§ 455.23)

The information collection activities associated with the proposed amendments to 42 CFR 455.23 are exempt from the PRA pursuant to 44 U.S.C. 3518(c)(1), which exempts from PRA coverage collections of information obtained as part of an agency's administrative enforcement activities, during the conduct of a Federal criminal investigation or prosecution, or during the disposition of a particular criminal or civil matter by or for a Federal agency. Specifically--

The proposed revisions at § 455.23(a)(1)(i), § 455.23(d)(4), § 455.23(e)(1)(i), and § 455.23(g)(3) involve the collection and exchange of information directly related to the investigation and adjudication of credible allegations of fraud (CAF) in the Medicaid program. The documentation, verification, and reporting activities contemplated under these provisions — including written determinations regarding active investigations, case-specific verification of good cause exceptions, and payment suspension status reporting — are conducted in connection with the investigation and potential prosecution of fraud against the Medicaid program and therefore fall within the scope of this exemption.

Although the following activities are not subject to PRA review, CMS provides the following summary for transparency and public awareness in Table C-A6.

TABLE C-A6: MEDICAID PAYMENT SUSPENSIONS

Regulatory Provision	Information Activity	Frequency	Respondents
§ 455.23(a)(1)(i)	Recordkeeping of accepted external CAF determinations	Per CAF referral accepted	SMAs
§ 455.23(d)(4)	Written determination and quarterly redetermination that CAF remains under active investigation	Per suspension; quarterly	SMAs
§ 455.23(e)(1)(i)	Case-specific good cause exception verification and documentation; reporting to CMS	Per good cause exception invoked	SMAs/MFCUs
§ 455.23(g)(3)	Quarterly payment suspension activity reporting to CMS	Quarterly	SMAs

Because the information collection activities described above are exempt from the PRA, no OMB control number is required for any of the proposed provisions. States are not required to display an OMB control number in connection with any documentation or reporting activities undertaken in accordance these regulations.

Because these provisions are exempt from the PRA, CMS is not required to estimate or publish a burden associated with the information activities described herein. Nevertheless, CMS notes that the administrative activities contemplated under these provisions are expected to impose minimal incremental burden on State Medicaid agencies (SMAs), as the underlying data and case tracking infrastructure necessary to support these activities are already maintained by States in connection with their existing Medicaid program integrity obligations. These are discussed in the Regulatory Impact Analysis section of this proposed rule. CMS remains committed to minimizing administrative burden on States consistent with the program integrity objectives of these proposed changes.

As stated in § 455.23(a), a SMA must suspend all Medicaid payments to a provider when there is pending an investigation of a credible allegation of fraud (CAF) under the Medicaid program against an individual or entity unless it has good cause to not suspend payments or to suspend payment only in part.

The burden associated with the proposed updates is the time and effort necessary for a SMA to report to CMS more frequently and coordinate with law enforcement agencies more frequently and with potentially more granular information. This collection of information requirement is PRA-exempt under 5 CFR 1320.4(a)(2).

g. ICRs Regarding National Provider Identifier (NPI) Requirements for Medicaid Providers (§ 455.440)

To derive average costs and savings, we used data from the U.S. Bureau of Labor Statistics' (BLS') May 2025 National Occupational Employment and Wage Statistics for all wage estimates (*https://www.bls.gov/oes/tables.htm*). In this regard, the following table presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs[206] (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE C-A7: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupational Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)	Number of Hours	Total
Office and Administrative Support Workers, All Other	43-9199	23.40	23.40	46.80	2.5	**$117**
Home Health and Personal Care Aides	31-1120	17.36	17.36	34.72	426,624	**$14,812,385**
IT Staff *	29-9021	$36.04	$36.04	$72.08	1,190	**$85,775**
Total					427,816.5	$14,897,224

* *Note: The system update costs involve a wide range of professionals as detailed in the ICR analysis. For simplicity, the total cost for that activity is presented in aggregate in the summary table.*

For States and the private sector, the employee hourly wage estimates have been adjusted upwards by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

To estimate the financial burden on States, it was important to consider the Federal government's contribution to the cost of administering the Medicaid program. The Medicaid

206 *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

FMAP that is established for each State is based on the per capita income in the State as compared to the national average. Medicaid FMAPs range from a minimum of 50 percent in States with higher per capita incomes to a maximum of 83 percent in States with lower per capita incomes but exceptions to the regular FMAP rate exist for certain States, situations, populations, providers, and services. For Medicaid, all States generally receive a 50 percent FMAP for administration. States also receive higher Federal matching rates for certain systems improvements, redesign, or operations. To determine the Federal contribution to the costs of administering the Medicaid program for purposes of estimating State burden with respect to the collections of information, we elected to use the higher end estimate that the States would contribute 50 percent of the costs. This assumption represents the upper bound of potential State burden, recognizing that the actual share is often lower once enhanced Federal match rates are applied.

2. National Provider Identifiers (NPIs) for Medicaid Providers

This section discusses the information collection requirements (ICRs) and burden associated with our proposed requirement that State Medicaid agencies collect, maintain, and use National Provider Identifiers (NPIs) for all Medicaid providers eligible to obtain an NPI as a covered health care provider under 45 CFR part 162.

This provision imposes ICR burden on two distinct populations: (1) State Medicaid agencies, which must identify providers lacking an NPI, conduct outreach, and update their systems; and (2) individual Medicaid providers who must apply for an NPI. The burden is primarily a one-time cost during the implementation period.

a. State Medicaid Agency Burden

We estimate a total one-time burden on State Medicaid agencies of 1,192.5 hours at a cost of $1,056,898, accounting for a 50 percent Federal administrative match for State costs. This burden consists of the following activities:

- **Identification of Providers Lacking an NPI:** States must review their provider files

to identify enrolled providers who are eligible for an NPI but do not have one on file. Based on data from the 10 States that do not already require NPIs for PCAs, we estimate approximately 1.28 million providers nationwide (primarily personal care attendants and other non-traditional providers) lack an NPI. We estimate this review will take one staff member 0.25 hours per State, performed by an Administrative Support Worker.

- *Total Hours:* 10 Administrative Support Workers × 0.25 hr/provider = 2.5 hours
- *Total Cost:* 2.5 hr × $46.80/hr = $117
- **Provider Outreach:** States will need to conduct outreach to the identified providers to inform them of the new requirement. We assume a single, batched communication effort requiring 0.1 hours per staff member for 10 States, performed by an Administrative Support Worker.

++ *Total Hours:* 10 staff members × 0.1 hr x 1,280,000 providers = 128,000 hours

++ *Total Cost:* (128,000 hr divided by 10 States) × $46.80/hr = $599,040

- **System Updates for Consistent NPI Use:** States that currently do not require NPIs for PCAs will need to ensure their Medicaid Enterprise Systems (MES) and related processes are updated to consistently use the NPI as the authoritative identifier across all functions. We estimate this one-time effort will require 119 hours per State, involving a mix of IT, management, and compliance staff.

++ *Total Hours:* 119 hours per State x *10* States = *1,190* hours

++ *Total Cost:* Based on the detailed occupational mix in the ICR, the aggregate cost is $*8,578* per State, for a total of $*85,775*.

b. Individual Provider Burden

We estimate that 1.28 million Medicaid providers will need to newly apply for an NPI through the National Plan and Provider Enumeration System (NPPES). This burden is accounted for under the existing NPPES collection (OMB Control No. 0938-0931; Expiration date: March 31, 2028) but is presented here for transparency. We estimate the application takes 20 minutes

(0.3333 hours), performed by the provider (approximated as a Home Health/Personal Care Aide wage).

- *Total Hours:* 1,280,000 providers × 0.3333 hr/provider = 426,624 hours
- *Total Cost:* 426,624 hr × $*34.72*/hr = $14,812,385

TABLE C-A8: SUMMARY OF BURDEN ASSOCIATED WITH THE NPI REQUIREMENTS

Requirement	No. of Respondents (States)	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Cost ($)	Federal Cost ($)
State Agency: Identification of Provider Gaps	10*	1,280,000	Once	0.25	320,000	46.80	117	58.5	58.5
State Agency: Provider Outreach	10*	1,280,000	Once	0.1	128,000	46.80	599,040	299,520	299,520
State Agency: Cross-System Updates	10*	10*	Once	119	1,190	72.08	85,775	8,578	77,197
State Subtotal	10*	2,560,010		119.35	449,190	165.68	385,985	328,746.30	356,712.20
Provider: NPI Application (Cross-Referenced)	1,280,000	1,280,000	Once	0.33	426,667	34.72	14,812,385		
TOTAL	**1,280,010**	**3,840,010**		**119.68**	**880,617**	**N/A**	**15,892,397**	**328,746.30**	**356,712**

*The same 10 States are performing these actions and are therefore only counted once.

c. ICRs Regarding Requirements for Program Integrity Corrective Action Plans (§ 455.600 *et seq.*)

The following proposed changes will be submitted to OMB for review under control number 0938-AV97 (CMS-6098).

As discussed in section III. of this proposed rule (Medicaid and CHIP Program Integrity Proposals), CMS conducts program integrity audits to assess State compliance with applicable Federal Medicaid program integrity requirements and identify programmatic vulnerabilities. Although CMS currently works with States to address findings identified through these audits, existing regulations do not establish standardized requirements governing when a State must develop a corrective action plan in response to findings identified through a CMS program integrity audit, the required contents of such a plan, or CMS review and oversight of its implementation.

Therefore, we propose at § 455.602 to establish requirements governing Program Integrity Corrective Action Plans (Program Integrity CAPs). Under the proposal, following a CMS program integrity audit, the final audit report would specify whether CMS requires the State to develop a Program Integrity CAP and would identify the findings of noncompliance that

the State must address through the CAP. CMS would determine whether a CAP is required based on the circumstances identified through the audit.

If a Program Integrity CAP is required, the State would be required to develop and submit a single CAP addressing the findings identified by CMS for corrective action. The CAP would be required to include the elements specified in new § 455.602(b), including a root cause analysis; the corrective actions the State would implement to address the identified findings and come into compliance; an implementation schedule and monitoring plan; and a plan for evaluating the effectiveness of the corrective actions. States would be required to submit a Program Integrity CAP to CMS no later than 30 calendar days after the date of the final audit report, and CMS would review the CAP to determine whether it satisfies the regulatory requirements and adequately addresses the applicable audit findings. If necessary, CMS could return the CAP to the State with feedback and require revision and resubmission. The State would also be required under § 455.602(c)(2) to provide updates on Program Integrity CAP implementation progress at each milestone timeframe identified in the implementation schedule for each corrective action and upon request by CMS. These updates would include the State's progress in implementing the corrective action in accordance with the approved implementation schedule and information regarding the effectiveness of the corrective action in rectifying the applicable finding or findings of noncompliance.

We believe these requirements would impose additional information collection burden on States that CMS requires to develop and implement a Program Integrity CAP. Based on our experience with existing[207] corrective action processes, we estimate that a State would require an average of 30 hours to develop and submit a Program Integrity CAP. We estimate that this work would be performed by a Claims Adjuster, Appraiser, Examiner, and Investigator at an adjusted hourly wage of $77.38. Actual burden could vary depending on the number and complexity of

207 CMS is requesting approval of a revision to the information collection currently approved under OMB control number 0938-1012 (Expiration date: November 30, 2027) associated with the existing PERM CAP requirements. The revision reflects changes to State submission requirements and the associated burden estimates. CMS requests a three-year approval period for the revised collection.

findings CMS requires the State to address and whether revisions to the CAP are necessary.

Because this is a new proposal, we do not yet have reliable data on the number of States that CMS would require to submit a program integrity CAP annually. For purposes of estimating the upper bound of potential annual burden, we estimate that CMS could conduct program integrity audits involving approximately 17 States annually. Because we cannot predict how many of those audits would result in CMS requiring a CAP, we conservatively assume for purposes of this burden estimate that CMS would require each of the 17 audited States to submit one Program Integrity CAP annually. This assumption is made solely for purposes of estimating potential burden and does not mean that CMS would require a CAP following every program integrity audit**.**

Under this assumption, we estimate an annual burden of 510 hours (17 States x 30 hr) and $39,463 (510 hr x $77.38/hr) associated with developing and submitting program integrity CAPs. Accounting for the 50 percent Federal administrative match, the total State cost is adjusted to $19,731 ($39,463 x 0.50). We summarize the total burden below in Table C-A9.

TABLE C-A9: SUMMARY OF BURDEN ASSOCIATED WITH PROGRAM INTEGRITY CAP REQUIREMENTS

Requirement	No. of Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Cost ($)	Federal Cost ($)
Development of a Program Integrity CAP (§ 455.600 *et seq.*)	17 States	17	Annual	30	510	77.38	39,463	19,731	19,731
TOTAL	17 States	17	Annual	30	510	77.38	39,463	19,731	19,731

d. ICRs Regarding Medicaid and CHIP Beneficiary Eligibility Audits (§ 455.700, *et seq.*)

The following proposed changes will be submitted to OMB for review under control number 0938-TBD (CMS-10936).

This rule proposes to establish a new Medicaid and CHIP beneficiary eligibility audit program under part 455, subpart H (§ 455.700 *et seq)*. The beneficiary eligibility audits offer Federal oversight of States' Medicaid and CHIP eligibility determination processes. By codifying the beneficiary eligibility audits, we intend to increase States' understanding of audit requirements and procedures as future audit findings could result in disallowances if this rule is

finalized as proposed. Additionally, in conjunction with our proposal to deregulate the MEQC program, we expect that the additional burden from the eligibility audits will be minimal for States, since these audits are conducted by CMS and its Federal contractors.

As discussed in section III. G. of this proposed rule, we would conduct a risk-based analysis to select high-risk States for audits each year. However, at a minimum, all 50 States and the District of Columbia would undergo an eligibility audit at least once every 5 years. As this is a new proposal, we do not yet have reliable data on the number of Medicaid and CHIP eligibility audits we would conduct annually. We currently estimate that 15 States will be selected each year for an eligibility audit.[208] As outlined in proposed § 455.704(b), each audited State would be required to provide requested eligibility and enrollment data and documentation to CMS; assign at least two subject matter experts (SME) to navigate the necessary information contained in the State's eligibility and enrollment system(s) for the sampled cases in coordination with the auditors; provide requested copies of additional eligibility case records and any other necessary documentation to CMS and its Federal contractors; provide a written response to each eligibility error in our draft report; and develop and submit corrective action plans (CAPs) for approval to address identified eligibility errors, where applicable.

Sections 1902(a)(6) and (a)(75) of the Act allow CMS to require States to submit data and documentation for CMS to evaluate State eligibility determinations for compliance with Federal requirements. As discussed in section H of the preamble and proposed at §§ 455.704 and 455.710, States would be required to submit the following data and documentation to CMS within 10 business days of receiving the engagement letter unless granted an extension by CMS:

- Enrollment totals of individuals applying for and enrolled in Medicaid and CHIP
- Eligibility universe data
- State policy and operations manuals

208 The number of audits conducted annually is subject to change based on available funding. 15 States is only an estimate. At a minimum, 10 States will be audited every year.

- Eligibility training and guidance materials
- State verification plans
- Any other data specified by CMS to review State eligibility processes

We estimate that it would take a Computer Systems Analyst 40 hours at $110.20/hr to collect and submit the initial data and documentation to CMS, including the enrollment data and eligibility case records. In addition, we estimate it will take a General and Operations Manager 4 hours at $129.74/hr to review the initial data and approve the submission of the requested data to CMS. In aggregate, we estimate an annual cost of $73,905 (15 x [(40 hr x $110.20/hr) + (4 hr x $129.74/hr)]). Accounting for a 50 percent Federal administrative match, the total State annual share is adjusted to $36,953 ($73,905 x 0.50).

We estimate that it would take two State eligibility interviewers a combined 375 hours at $53.94/hr to guide auditors through the State's eligibility and enrollment system(s).[209] The designated eligibility interviewers will navigate the State's system(s) at the request of CMS auditors and provide the relevant documentation for each of the 500 cases selected for the audit (specifically, 200 active Medicaid cases, 50 negative Medicaid cases, 200 active CHIP cases, and 50 negative CHIP cases). In aggregate, we estimate an annual burden of 5,625 hours (15 States x 375 hr) at a cost of $303,413 (5,625 hr x $53.94/hr) for the State SMEs to guide CMS auditors through the State's eligibility and enrollment system(s). Accounting for the 50 percent Federal administrative match, the total estimated State cost is adjusted to $151,707 ($303,413 x 0.50).

We estimate that it would take a Computer Systems Analyst 12 hours at $110.20/hr to provide any additional data and documentation pertaining to the sampled cases during the audit, including enrollment data and eligibility case records upon CMS' written request. We estimate it will take a General and Operations Manager 2 hours at $129.74/hr to review the additional data

209 For the proposed eligibility audits, States do not need to establish new eligibility and enrollment systems or train auditors on current systems. Instead, States are required to assign SMEs to navigate the existing systems with the CMS auditors. Both SMEs don't need to present for each individual case review. Instead, we suggest that the assigned SMEs participate in different case reviews preferably even at the same time.

and documentation and approve the submission to CMS. In aggregate, we estimate an annual cost of $23,729 (15 x [(12 hr x $110.20/hr) + (2 hr x $129.74/hr)]). Accounting for a 50 percent Federal administrative match, the total State share is adjusted to $11,865 ($23,729 x 0.50).

We estimate that it would take a General and Operations Manager 8 hours at $129.74/hr to respond to the beneficiary eligibility audit draft report indicating agreement or disagreement with each of the identified eligibility errors. In aggregate, we estimate an annual burden of 120 hours (15 States x 8 hr) at a cost of $15,569 (120 hr x $129.74/hr). Accounting for the 50 percent Federal administrative match, the total State cost is adjusted to $7,785 ($15,569 x 0.50).

At § 455.712, we propose that each audited State develop a CAP to address identified eligibility errors and submit it to us for approval. We estimate that it would take a Business Operations Specialist, All Other 40 hours at $90.36/hr to develop and submit a CAP for approval. In aggregate, we estimate an annual burden of 600 hours (15 States x 40 hr) at a cost of $54,216 (600 hr x $90.36/hr). Accounting for the 50 percent Federal administrative match, the total State cost is adjusted to $27,108 ($54,216 x 0.50). We summarize the total burden in Table C-A10.

TABLE C-A10: SUMMARY OF BURDEN ASSOCIATED WITH THE MEDICAID AND CHIP BENEFICIARY ELIGIBILITY AUDIT REQUIREMENTS

Requirement	No. of Respondents	Total Responses	Frequency	Time per Response (hr)	Total Time (hr)	Wage ($/hr)	Total Cost ($)	State Cost ($)	Federal Cost ($)
Initial Data Collection and Submission (§ 455.700, *et seq.*)	15	15	Annual	44	660	Varies	73,905	36,953	36,953
Eligibility and Enrollment System(s) Navigation (§ 455.700, *et seq.*)	15	15	Annual	375	5,625	53.94	303,413	151,707	151,707
Additional Data Collection and Submission	15	15	Annual	14	210	Varies	23,729	11,865	11,865
State Response to Draft Report (§ 455.700, *et seq.*)	15	15	Annual	8	120	129.74	15,569	7,785	7,785
CAP Development and Submission (§ 455.700, *et seq.*)	15	15	Annual	40	600	90.36	54,216	27,108	27,108
TOTAL	15	15	Annual	481	7,215	N/A	470,832	235,418	235,418

e. ICRs Regarding Medicaid Beneficiary Eligibility-Related Disallowances (§ 455.800, *et seq.*)

This rule proposes to remove the current disallowance regulation at § 431.1010 and establish new disallowance regulations at part 455, subpart I (§ 455.800, *et seq*.) that would apply to the Medicaid beneficiary eligibility audit program proposed under part 455, Subpart H. Under the new disallowance framework, we are proposing that States undergoing Medicaid

beneficiary eligibility audits would face full or partial eligibility-related disallowances if their calculated eligibility error rates exceed the 3-percent allowable threshold, unless they are determined to meet the new good faith waiver requirements in § 455.804. We do not believe that the proposed changes would impose any new or revised collection of information requirements or burden, including those associated with the creation or revision of State plans or other State-owned policy documents. Furthermore, we believe that the proposed disallowance regulations are exempt from PRA requirements because under 5 CFR 1320.3(c) a collection of information applies when imposed on "10 or more persons," and fewer than 10 States would be subject to a potential disallowance under section 1903(u) of the Act each year. Thus, eligible to submit evidence for evaluation of good faith waiver eligibility under new § 455.804. We anticipate that fewer than 10 States will be affected by these new requirements, since we plan to conduct a maximum of 15 Medicaid beneficiary eligibility audits each year, and only audited States with eligibility error rates calculated using the lower limit of the 90 percent confidence interval above the 3-percent statutory threshold will be subject to potential disallowances. As a result, the proposed eligibility-related disallowance framework would not be subject to the requirements of the PRA.

f. ICRs Regarding Medicaid Fee-For-Service Overpayment Reporting (60-Day Rule) (§ 455.900, *et seq.*)

Section 1128J(d) of the Act requires a person who has received an overpayment to report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate. The Act also requires that a notification be made to the payer, in writing, of the reason for the overpayment. Section 1128J(d)(2) of the Act requires persons receiving overpayments under Medicaid or Medicare to report and return the overpayment by the later of: (1) 60 days after the date on which the overpayment was identified; or (2) the date any corresponding cost report is due, if applicable. Section 1128J(d)(3) of the Act specifies that any overpayment retained by a person after the deadline for reporting and returning an overpayment

is an obligation subject to enforcement under the FCA (as defined in 31 U.S.C. 3729(b)(3)). The term "person" refers to any provider of services, supplier, Medicaid managed care organization, Medicare Advantage Organization, or Prescription Drug Plan sponsor. Section 1128J(d)(4)(C)(ii) of the Act excludes beneficiaries from the definition of person.

As discussed in section I.B.4.f. of this proposed rule, even without a final rule, all interested parties are already subject to the statutory requirements found in section 1128J(d) of the Act and could face potential FCA liability, CMPL liability, and exclusion from Federal health care programs for failure to report and return an overpayment. This proposed rule provides clarity and consistency in the reporting and returning of overpayments in Medicaid FFS by outlining these requirements in regulation. We believe that this change would spur persons to be more diligent in reporting and returning overpayments in the Medicaid FFS program. That would likely increase the overpayments that States collect and the associated FFP they return, as well as the reporting that States must perform related to these returned overpayments.

Despite the absence of a strong basis for estimating the magnitude of this clarification's effect on the reporting and returning of overpayments in the Medicaid FFS program, we believe that we can use existing data to approximate what the potential impact may be, both on persons eligible to receive Medicaid funds (who would be responsible for identifying and returning the overpayments to the State) and on States (which would need to return the Federal share of those overpayments to us through the standard CMS-64 reporting process that is currently approved by OMB under control number 0938-1265). As for the impact on persons eligible to receive Medicaid funds, we believe that the PERM improper payment rates provide us with national context on improper payment rates for the Medicaid FFS component of the PERM measurement, which was approximately 5 percent for FY 2024. Given that the total amount of projected improper payments reported was $31.10 billion, we can calculate the FFS component to be $11.23 billion. Although the actual improper payment rates for individual States can vary quite widely, we believe that it is reasonable for us to use the national numbers to approximate

the impact on an average State. The CMS-64 does not track overpayments by providers; however, data exists related to PERM overpayment letters sent to States for reporting on the CMS-64. Under the PERM medical review and data processing recovery process, recovery amounts are based on payments identified in individual sampled claims. The total Federal share of Medicaid PERM overpayments identified for recovery for RY 2025 is $1,264,636. This amount is not extrapolated to the national payment universe. States report the Federal share through CMS-64 adjustments. Eligibility-related improper payments are addressed through the separate disallowance framework under section 1903(u) of the Act, including the 3 percent threshold and the good faith waiver provisions.

This proposed regulation may also have an impact on the States themselves, as they would be responsible for reporting and returning the Federal share through the standard CMS-64 reporting process, but we believe that the impact would be minimal because States already report and reconcile expenditures and recoveries through the CMS-64, which CMS reviews and finalizes quarterly. Given that States are already responsible for reporting and returning the Federal share of overpayments made in their FFS programs, we do not believe that there would be an appreciable increase in burden by clarifying these requirements in regulation, even if the regulation leads to increased reporting by providers. The steps to report this information in the CMS-64 are well established and would not require changes as a result of this regulation. We welcome public comments on our assumptions.

g. ICRs Regarding Enhanced Electronic Visit Verification (EVV) Requirements (42 CFR §§ 447.45 and 455.14)

This rule proposes to amend §§ 455.14 and 447.45(f) to require SMAs to use EVV data for certain program integrity and improper payment oversight activities. We propose to amend § 455.14 to require that SMAs incorporate a review of EVV records as part of preliminary investigations into potential Medicaid fraud or abuse involving home-based service providers subject to Federal and State EVV requirements. We also propose to amend § 447.45 to require

that SMAs verify that billed services are supported by EVV records during prepayment claims review, where applicable under Federal or State requirements. Specifically, we are proposing that for services subject to EVV, States verify during prepayment claims review that the following data elements are supported by an EVV record: (1) the type of service performed; (2) the individual receiving the service; (3) the date of service; (4) the location of service delivery; (5) the individual providing the service; and (6) the time the service begins and ends.

We do not believe that the proposed changes to §§ 447.45 and 455.14 would impose any new collection of information requirements. These regulatory changes do not require SMAs to report any new information to CMS or the public, just to update internal program integrity investigation and prepayment review processes. Additionally, the proposed requirement for SMAs to review available EVV data during preliminary investigations of applicable in-home service providers would be exempt from PRA requirements in accordance with § 1320.4(a)(2), which grants an exception to collection of information requirements during an investigation involving an agency against specific individuals or entities. As a result, the proposed EVV requirements are not subject to the requirements of the PRA.

3. Medicare Advantage and Medicare Part D Program Integrity

a. ICRs Relating to Risk Adjustment Data Validation (RADV) (42 CFR 422.300, 422.310, and 422.311)

Section 1853(a)(1)(C) of the Act requires that CMS risk-adjust payments made to MA organizations. Risk adjustment strengthens the MA program by ensuring that accurate payments are made to MA organizations based on the health status and demographic characteristics of their enrolled beneficiaries, and that MA organizations are paid appropriately for their plan enrollees (that is, less for healthier enrollees who are expected to incur lower health care costs, and more for less healthy enrollees who are expected to incur higher health care costs). Making accurate payments to MA organizations also ensures we are safeguarding Federal taxpayer dollars.

The diagnosis data that MA organizations submit to CMS does not undergo a validation

review by CMS before being relied on by CMS to calculate each enrollee's risk score and make payments. CMS conducts post-payment audits of diagnosis data submitted by MA organizations from a selection of MA organizations for specific payment years to ensure that the diagnoses they submitted are supported by their enrollees' medical records. These audits are called contract-specific MA Risk Adjustment Data Validation (RADV) program audits. CMS conducts RADV audits, which require MA organizations to submit a sample of medical records to CMS for validation of risk adjustment data pursuant to 42 CFR 422.310(e).

In the event MA organizations experience extraordinary circumstances beyond their control that may make it difficult to meet medical record submission or other audit requirements, they may request a hardship exception. MA organizations requesting a hardship exception are required to submit supporting documentation that clearly demonstrates extraordinary circumstances exists and includes all relevant details required for CMS to comprehensively assess the incident or issue. Supporting documentation includes, but is not limited to, any communications associated with the incident and all available evidence substantiating that the incident occurred.

Collection of information to conduct contract-specific RADV audits was previously included in CMS-10191, which expired on June 30, 2023. CMS-10191 has since been replaced by a more streamlined collection of information under OMB control number: 0938-1395 (Expiration date: January 31, 2027)[210]. The information collection request is specific to CMS' compliance audits designed to ensure MA organizations comply with all Medicare Parts C and D program requirements. This is accomplished by conducting audits that focus on high-risk areas with the greatest potential for beneficiary harm, thereby strengthening CMS' oversight and accountability framework for MA organizations. Therefore, CMS is proposing a new collection that includes RADV audits, as CMS has determined that the collection of information pursuant

210 https://www.federalregister.gov/documents/2026/07/06/2026-13603/agency-information-collection-activities-submission-for-omb-review-comment-request.

to contract-specific RADV audits should be included in its own dedicated PRA package.

The discussion in this section informs the public of the information collected in connection with and to comply with contract-specific RADV audit requirements.

b. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2025 National Occupational Employment and Wage Estimates for all salary estimates (https://data.bls.gov/oes/#/area/0000000/2025). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage. We selected the following personnel for our burden estimate based on our previous experiences conducting similar Part C program audits.

TABLE C-A11 NATIONAL OCCUPATIONAL MEAN HOURLY WAGE AND ADJUSTED HOURLY WAGE

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr.)	Fringe Benefit ($/hr.)	Adjusted Hourly Wage ($/hr.)
Medical and Health Services Managers	11-9111	67.77	67.77	135.54
Legal Support Workers, All Other	23-2099	43.10	43.10	86.20
Medical Records Specialists	29-2072	27.30	27.30	54.60
Medical Secretaries and Administrative Assistants	43-6013	22.50	22.50	45.00

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

The following table shows the burden (hours) and total cost by occupation, and total cost for an average audited contract. The average hourly wage for the RADV audit information collection is $52.05, which is derived by dividing Total Cost ($37,946.48) by the Burden (729) (see Table C-A12).

TABLE C-A12 NATIONAL OCCUPATIONAL MEAN HOURLY WAGE AND ADJUSTED HOURLY WAGE

Occupation	Adj Hourly Wage	Burden (Hours)	Total Cost
Medical and Health Service Managers	$135.54	21.4	$2,900.56
Legal Support Workers, All Other	$86.20	21.4	$1,844.68
Medical Records Specialists	$54.60	241.9	$13,207.74
Medical Secretaries and Administrative Assistants	$45.00	444.3	$19,993.50
Total		**729**	**$37,946.48**

Table C-A13 shows the burden (hours) and total cost by occupation, and total cost for an average audited contract. The average hourly wage for the Hardship Exception information collection is $59.55, which is derived by dividing Total Cost ($595.47) by the Burden (10).

TABLE C-A13 NATIONAL OCCUPATIONAL MEAN HOURLY WAGE AND ADJUSTED HOURLY WAGE

Occupation	Adj Hourly Wage	Burden (Hours)	Total Cost
Medical and Health Service Managers	$135.54	0.5	$67.77
Legal Support Workers, All Other	$86.20	1.5	$129.30
Medical Records Specialists	$54.60	4	$218.40
Medical Secretaries and Administrative Assistants	$45.00	4	$180.00
Total		**10**	**$595.47**

c. Burden Summary

Based on our audit strategy, contract-specific audits are conducted for each payment year. For each MA organization, we estimate an average of 729 hours for administrative and systemic work to assemble the requested information, review the information for completeness, and submit the information to CMS.

CMS announced an aggressive strategy to enhance and accelerate MA audits in May 2025.[211] This strategy included increasing the number of eligible MA contracts selected for audits. CMS identified enrollees that it believes are at most risk for being associated with payment error in MA and focused audits on these enrollees. However, some contracts that did not have enrollees that met the top 25 percent threshold were subject to random selection for audits. CMS estimates it will include approximately 492 contracts for payment years 2022 and

211 https://www.cms.gov/newsroom/press-releases/cms-rolls-out-aggressive-strategy-enhance-accelerate-medicare-advantage-audits

2023 RADV audits and approximately 590 MA contracts in payment year 2025 and later payment years using this methodology.

Based on prior contract-specific RADV audits, approximately 50 percent of MA organizations' contracts submit hardship exception requests. On average, it takes an MA organization 10 hours to review the requirements and complete and submit a hardship exception request with all required supporting documentation. Information collected by MA organizations during an audit will also be used to compile the information as part of a hardship exception request, reducing duplicative effort.

MA organizations that want to submit hardship exception requests must submit required information and upload relevant supporting documents in the RADV secure system, the Centralized Data Abstraction Tool (CDAT). Each hardship exception request must include hardship justification and supporting documentation. Additionally, MA organizations must designate the type of hardship exception request they are submitting: contract, enrollee, or HCC.

TABLE C-A14: TOTAL COST OF PROPOSED POLICIES BY YEAR (in Millions)

ICR	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
RADV Audit	$59.73	$22.39	$22.39	$22.39	$22.39	$22.39	$22.39	$22.39	$22.39	$22.39	$261.24
Hardship Exceptions	$0.47	$0.18	$0.18	$0.18	$0.18	$0.18	$0.18	$0.18	$0.18	$0.18	$2.09
Total	$60.20	$22.57	$22.57	$22.57	$22.57	$22.57	$22.57	$22.57	$22.57	$22.57	$263.33

Proposed Information Collection Requirements and Burden

b. ICRs RADV Data Validation (§ 422.300)

The proposed changes will be submitted to OMB for review under control number 0938-NEW (CMS-10980).

CMS conducts contract-specific RADV audits each payment year on MA contracts meeting its audit criteria, covering approximately 590 MA contracts per payment year. Each audited HCC requires one submitted medical record, totaling approximately 336 medical records per contract. CMS estimates 729 hours per contract to respond to the audit (see Table C-A15).

TABLE C-A15: RADV AUDIT ICRs

Information Collection	No. of Respondents	Responses (per Respondent)	Total Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($/hr)	Total Cost
RADV audits	590	336	198,240	729	430,110	$52.05	$22,388,421

c. ICRs Extrapolation (§ 422.310(e))

The proposed provision would not impose any new or revised information collection requirements (that is, reporting, recordkeeping, or third-party disclosure requirements) or burden since the utilization of extrapolation will not affect the existing process for MA organizations submitting medical record documentation pursuant to RADV audits. Consequently, the provisions are not subject to the PRA.

d. ICRs Hardship Exception Request (§ 422.310(e)(1))

The proposed changes will be submitted to OMB for review under control number 0938-NEW (CMS-10980).

Based on prior contract-specific RADV audits, approximately 50 percent of MA organizations' contracts submit a hardship exception request. On average, an MA organization takes 10 hours to review the requirements, complete, and submit a hardship exception request with all required supporting documentation. Information MA organizations collect during an audit will also be used to compile the hardship exception request, reducing duplicate effort.

TABLE C-A16: HARDSHIP REQUEST ICRs

Information Collection	No. of Respondents	Responses per Respondent	Total Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)
Hardship exception request	295	1	295	10	2,950	59.55	175,664

e. ICRs RADV Audit Dispute and Appeal Procedures (§ 422.311)

Upon conclusion of a RADV audit, MA organizations are afforded an opportunity to appeal their audit findings pursuant to 42 CFR 422.311(c). In accordance with the implementing regulations at 5 CFR 1320.4(a)(2), the burden associated with information collected during the conduct of an administrative action is not subject to the PRA. Additional information collected by CMS from MA organizations in connection with RADV appeals is exempt from the PRA because the data collection is a result of an administrative action. Therefore, we have not provided burden estimates for this task.

f. ICRs Relating to Mandatory Reporting of Fraud, Waste, and Abuse (42 CFR 422.500, 422.503 and 423.504)

The following changes will be submitted to OMB for approval under control numbers 0938-1383 (CMS-10724) for MA organizations and 0938-1262 (CMS-10517) for Part D plans.

The modified sections at 42 CFR 422.503(b)(4)(vi)(G)(*3*)(*i*) and 423.504(b)(4)(vi)(G)(*3*)(*i*) and 42 CFR 422.503(b)(4)(vi)(G)(*3*)(*iii*) and 423.504(b)(4)(vi)(G)(*3*)(*iii*) will require MA organizations and Part D plan sponsors, respectively, to have procedures to identify and report to CMS or its designee: (1) any payment suspension implemented by an MA organization or Part D plan sponsor, pending investigation of credible allegations of fraud, which must be implemented in the same manner as the Secretary's requirement under section 1862(o)(1) of the Act; and (2) any substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste or abuse for initiating or assisting investigations conducted by CMS, or its designee, a Medicare

program integrity contractor, or law enforcement partners.

Beginning January 1, 2022, CMS implemented requirements of sections 2008 and 6063 of the SUPPORT Act, which included the establishment of the HPMS FWA Reporting Module. Since that time, Medicare Part C and Part D plan sponsors have submitted referrals of payment suspensions for other provider types and substantiated or suspicious FWA at their discretion. As such, CMS is able to use the submission data as a method of estimating the number of referrals of substantiated or suspicious FWA to the HPMS FWA Reporting Module annually, through a frequency report.[212]

For calendar year 2025, individual MA organization and Part D plan sponsor contracts submitted 1,788 referrals for payment suspensions for credible allegations of fraud that were for all provider and supplier types, based on an HPMS frequency report. CMS then utilized the 2025 Quarterly FWA Reports to estimate that approximately 782 of those referrals were for payment suspensions of entities other than pharmacies. For the 2025 calendar year, based on an HPMS frequency report, individual MA organization and Part D plan sponsor contracts submitted 8,062 referrals of substantiated or suspicious FWA submissions to the HPMS FWA Reporting Module. These payment suspensions and substantiated or suspicious FWA submissions were made by 19 percent and 46 percent of the 2025 contracts, respectively. CMS believes it is reasonable to make a few assumptions:

- Not all contracts currently report referrals for payment suspensions based on credible allegations of fraud for providers and suppliers outside of pharmacies, as such reporting is not currently required.

- Not all contracts currently report referrals of substantiated or suspicious FWA to CMS, even when the referral meets the definition at 42 CFR 422.500 and 423.4, as such reporting is not currently required.

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212 A frequency report is an internal report CMS is able to pull within the HPMS FWA Reporting Module. It allows CMS to see, for a specified timeframe, the frequency a contract has made referrals for each reporting period.

- Not all contracts will have a referral each year that meets the definition at 42 CFR §§ 405.370, 455.2 and 423.4 for credible allegation of fraud.
- Not all contracts will have a referral each year that meets the definition at 42 CFR 422.500 and 423.4 for substantiated or suspicious FWA.
- The plan sponsors are already familiar with the HPMS FWA Reporting Module; therefore, the estimated burden is reasonably expected to be the same across all years. CMS expects no increased burden in the first year as there is no need to establish new processes for reporting.

Given these assumptions, CMS believes that multiplying the number of payment suspensions by a factor of 5 and doubling the number of referrals received for substantiated or suspicious FWA in calendar year 2025 would be reasonable to estimate the number of submissions per calendar year and determine annual burden. We estimate that there would be 20,034 (782x5 + 8,062x2) referrals each calendar year. The burden consists of the time and effort needed to prepare and report the information for payment suspensions based on credible allegations of fraud and referrals of substantiated or suspicious FWA to CMS. The reporting across plan sponsors and contracts will not be consistent based on many varying factors such as size of beneficiary enrollment and internal policies and procedures. As such, CMS cannot reasonably estimate which plan sponsors may have higher or lower reporting. We propose to create an estimate based on average reporting across all plan sponsors. For the 2027 plan year, there are 769 MA organization and PDP contracts in total or 722 MAO contracts and 47 PDP contracts when separated. We estimate there will be approximately 26 annual referrals on average per plan sponsor (20,034 referrals/769 MA organizations and PDP plans). We estimate each referral would take approximately 30 minutes to complete, resulting in approximately 13 hours (26 annual referrals/0.5 hr) spent on referrals for each plan sponsor.

Therefore, we estimate it would take 722 MA organizations 9,386 hours (722 plans x 13 hrs/plan) at a cost of $1,027,016.12 (9,386 hrs * $109.42/hr for a management analyst using

2025 BLS wage estimates) to fulfill the reporting requirements annually as shown in Table C-A18.

We estimate it would take 47 Part D plan sponsors 611 hours (47 plans * 13 hrs/plan) at a cost of $66,855.62 (611 hrs * $109.42/hr) to fulfill the reporting requirements annually as shown in Table C-A18.

TABLE C-A18: MA ORGANIZATION AND PART D PLAN SPONSOR BURDEN ESTIMATES

Regulatory Citation	OMB Control Number	Response Summary	Total Number of Respondents	Time per Respondent (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Cost Annually ($)
§ 422.503(b)(4)(vi)(G)(*3*)	0938-1383	MA organizations report payment suspensions and FWA	722	13	9,386	109.42	1,027,016.12
§ 423.504(b)(4)(vi)(G)(*3*)	0938-1262	Part D plan sponsors report payment suspensions and FWA	47	13	611	109.42	66,855.62
TOTAL*			769	13	9,997	109.42	1,093,871.74

We solicit comments on our proposed provisions, burden estimates, and assumptions.

4. ICRs related to Medicare Provider Enrollment Provisions

This section discusses the ICR burdens associated with our proposed Medicare provider enrollment provisions. Two sets of provisions are addressed: (1) those that impose an ICR burden; and (2) those that do not but which require further explanation. Provisions that are not mentioned have no ICR impact. For purposes of obtaining approval from the Office of Management and Budget (OMB) for the following information collection requirements, all burden estimates are based on a standard 3-year approval.

Table C-A19 lists the Bureau of Labor Statistics (BLS) hourly wage estimates (see https://data.bls.gov/oes/#/area/0000000/2025) for the occupational categories used in this section.

TABLE C-A19: MAY 2025 BLS NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Office and Administrative Support Workers, All Other	43-9199	23.40	23.40	46.80
Business and Financial Operations Occupations	13-0000	45.78	45.78	91.56
General and Operations Managers	11-1021	64.87	64.87	129.74
Physicians	29-1210	133.30	133.30	266.60
Healthcare Diagnosing or Treating Practitioners	29-1000	63.46	63.46	126.92

a. Surety Bonds (§ 424.57(d)(16))

Under proposed new § 424.57(d)(16), CMS could decline to accept DMEPOS surety bonds from an authorized surety when the surety has not paid or satisfied an administratively final bond obligation that is owed to CMS. CMS notifies the surety in writing of its intention to

do so and gives the surety 15 days to submit a rebuttal.

In accordance with the implementing regulations of the PRA at 5 CFR 1320.4(a)(2), information collected as part of or subsequent to an administrative action is not subject to the PRA. We believe CMS' declining to accept DMEPOS surety bonds from an authorized surety when the surety has not paid or satisfied an administratively final bond obligation that is owed to CMS is an administrative action. Therefore, we are not assigning burden to the rebuttal process.

b. Reporting of Additional Information on the Form CMS-855S

We are proposing in new § 424.57(i) to require all DMEPOS suppliers to report on the Form CMS-855S application (or its successor form) all domestic and foreign entities and individuals that:

- Perform any marketing service of any type for the supplier.
- Furnish DMEPOS items or services to beneficiaries on the supplier's behalf, such as fulfillment companies.
- Are wholesalers from which the supplier purchases DMEPOS items for provision to the supplier's beneficiaries.

c. Initial Enrollments, Revalidations, Reactivations, and CIMOs

There are presently about 70,616 enrolled DMEPOS suppliers, with approximately 5,167 suppliers submitting initial enrollment applications each year. (This includes suppliers that are undergoing a § 424.551 CIMO.) Approximately 5,176 DMEPOS suppliers each year submit reactivation applications and 17,413 submit revalidation applications; reactivation and revalidation applications require completion of the entire Form CMS-855S.

Based on projections we have made regarding previous additions of data elements to the Form CMS-855S, we estimate that it would take the supplier 0.67 hours to prepare and provide this information. Consistent with prior Form CMS-855S burden estimates, we believe that office and administrative staff would gather and submit said data; hence, we will use Table C20's

$46.80 figure (with FBO) for such personnel. The resulting ICR burdens by application type can be found in Table C-A20.

TABLE C-A20: PROPOSED § 424.57() ICR BURDEN ESTIMATES FOR CERTAIN FORM CMS-855S CATEGORIES

Form CMS-855S Application Type	Annual Number of Submissions	Total Hour Burden (Annual Submissions x 0.67)	Total Cost Burden (Total Hour Burden x $46.80)
Initial (Including CIMOs)	5,167	3,462	$162,022
Reactivations	5,176	3,468	$162,302
Revalidations	17,413	11,667	$546,016
Total	**27,747**	**18,597**	**$870,340**

d. Changes of Information (COIs)

Among our proposals is that providers and suppliers must report any change in their enrollment information within 30 days of the change. This would include changes in § 424.57(i) data. As this is new data on the Form CMS-855S, we have no history we can use to reliably project the number of § 424.57(i) COIs that would be submitted. Solely to solicit comment to help us prepare an estimate, we tentatively project that 2,500 DMEPOS suppliers per year would submit such COIs and – in line with our current COI time estimates – that it would take each supplier 1 hour to do so.

We believe the supplier's office staff (with the $46.80 hourly wage) would prepare and submit these COIs. Consistent with current Form CMS-855S burden estimates: prepare and submit these COIs. Consistent with current Form CMS-855S burden estimates:

- The COI would be signed by either an authorized or delegated official of the supplier (if the latter is an entity) or the physician if the supplier is an individual.

- The applicable BLS wage categories for these signatories are: (1) General and Operations Managers (GOM) (for authorized officials and delegated officials as those terms are defined in § 424.502); and (2) Physicians. The mean GOM wage with FBO is $129.74; it is $266.60 for physicians.

- About 80 percent of the 1-hour COI burden would be incurred by the office employee in preparing and sending the COI. The manager or physician would incur the remaining 0.2 hours in reviewing and signing the COI.

- Approximately 75 percent of Form CMS-855S applications (including COIs) are submitted by DMEPOS supplier organizations and the remaining 25 percent by DMEPOS supplier physicians.

Applying an annual time burden of 2,500 hours (2,500 suppliers x 1 hour), the foregoing results in the following burden estimates.

TABLE C-A21: Proposed § 424.57(i) ICR Burden Estimates for Form CMS-855S COIs

Submitter	Total Hour Breakdown	Total Cost Breakdown
DMEPOS Supplier Entity	1,500 Hours for Office Staff (2,500 x 0.8 x 0.75) 375 Hours for Managers (2,500 x 0.2 x 0.75)	$70,200 (1,500 x $46.80) for Office Staff $48,653 (375 x $129.74) for Managers
DMEPOS Supplier Physician	500 Hours for Office Staff (2,500 x 0.8 x 0.25) 125 Hours for Physicians (2,500 x 0.2 x 0.25)	$23,400 (500 x $46.80) for Office Staff $33,325 (125 x $266.60) for Physicians
Totals	2,500	$175,578

e. Documentation Verifying Identity and Other Information (§ 424.510(d)(2))

Under existing § 424.510(d)(2)(ii), providers and suppliers (hereafter occasionally "providers") must submit all documentation required by CMS to uniquely identify the provider. Proposed revised § 424.510(d)(2)(ii) would: (1) list types of documentation that could fall within said paragraph's purview; and (2) clarify that § 424.510(d)(2)(ii) includes documentation pertaining to the provider's owners and managing employees. Current § 424.510(d)(2)(iii)(C), meanwhile, requires the provider to submit any other documentation needed to verify and confirm the information on the enrollment application, including documentation regarding ownership or management. Proposed revised § 424.510(d)(2)(iii)(C) would make clear that this includes domestic and foreign owners and managers.

We believe the documentation categories in existing § 424.510(d)(2)(ii) and (d)(2)(iii)(C) already effectively capture the documents we are proposing to reference in these paragraphs.

While this might indicate no additional ICR burden, it is possible that revised § 424.510(d)(2)(ii) and (d)(2)(iii)(C) would trigger additional documentation requests. We cannot predict the number of such requests or the types of documentation that would be involved. Yet we believe a general estimate, solely for purposes of this ICR section, is feasible.

Since the provider's office personnel would likely compile and provide this documentation, we will use the aforementioned $46.80 wage rate. We estimate that: (1) roughly 1,000 additional requests would be made annually; and (2) it would take the provider 15 minutes (0.25 hr.) to furnish the data. The annual burden would thus be 250 hours (1,000 x 0.25 hrs.) and $11,700 ($46.80 x 250).

f. ICRs Regarding the Enrollment of MA Providers, Suppliers, and First-Tier, Downstream, and Related Entities (FDRs) (§ 422.223)

We are proposing in new § 422.223 to require providers and suppliers that bill MA for services and items furnished to MA beneficiaries to be enrolled in Medicare fee-for-service (FFS) in order to receive payment. There are over 2 million providers and suppliers nationwide that are enrolled in Medicare FFS. Through our analysis of currently available MA encounter data, roughly 149,751 providers and suppliers that currently bill MA are not FFS-enrolled and would thus have to enroll under our proposed requirement. These providers and suppliers are of the types that would, per our internal data, complete the following applications according to the following estimates:

- Form CMS-855A (Medicare Enrollment Application: Institutional Providers (OMB Control No. 0938-0685)) - 6,409 providers and suppliers
- Form CMS-855B (Medicare Enrollment Application: Clinics/Group Practices and Other Suppliers (OMB Control No. 0938-1377)) - 28,693 suppliers
- Form CMS-855I (Medicare Enrollment Application: Physicians and Non-Physician Practitioners (OMB Control No. 0938-1355) --- 111,960 physicians and practitioners
- Form CMS-855S – 2,689 DMEPOS suppliers

Consistent with prior ICR estimates we have made, the hour burdens for completing these applications are 4 hours for the Form CMS-855A, 3 hours for the Form CMS-855B, 3 hours for the Form CMS-855I, and 3 hours for the Form CMS-855S. These forms are typically completed by office and administrative staff (Occupation Code 43-9199). The Forms CMS-855A, B, and S are signed by general and operations managers (Occupation Code 11-1021). About 75 percent of Form CMS-855I applications are signed by physicians and the remaining 25 percent by healthcare practitioners (Occupational Code 29-1000). Using the hourly wage figures in Table C-A22, this results in the following burden estimate over the first 3 years of the requirements.

TABLE C-A22: HOUR AND COST ESTIMATES IN FIRST 3 YEARS OF MA ENROLLMENT REQUIREMENT

Form Type	Hour Burden and Associated Wage	Total Number of Application Submissions	Total Hour Burden	Cost Per Application	Total Cost
CMS-855A	3.5 hrs (Office Staff ($46.80)) + 0.5 hours (Manager ($129.74))	6,409	25,636	$228.67 ((3.5 x $46.80) + (0.5 x 129.74))	$1,465,546
CMS-855B	2.5 hrs (Office Staff ($46.80)) + 0.5 hours (Manager ($129.74))	28,693	86,079	$181.87 ((2.5 x $46.80) + (0.5 x 129.74))	$5,218,396
CMS-855I	2.5 hrs (Office Staff ($46.80)) + 0.5 hours (Physician/$266.60 or Practitioner/$126.92)	111,960 (Physicians – 83,970 applications; Practitioners – 27,990)	335,880	Physicians - $250.30 ((2.5 x $46.80) + (0.5 x $266.60)) Practitioners - $180.46 ((2.5 x $46.80) + (0.5 x $126.92))	$26,068,766 (Physicians: $21,017,691 + Practitioners: $5,051,075)
CMS-855S	2.5 hrs (Office Staff ($46.80)) + 0.5 hours ((Manager ($129.74))	2,689	8,067	$181.87 ((2.5 x $46.80) + (0.5 x 129.74))	$489,048
Total	**N/A**	**149,751**	**455,662**	**N/A**	**$33,241,756**

The foregoing results in an average annual burden in the first 3 years of this requirement of 151,887 hours and $11,080,585. We request feedback from stakeholders as to the number of CMS-855 changes of information these newly enrolling providers and suppliers might submit during this 3-year period.

g. Medicaid or CHIP Denial and Termination Data (New § 455.418)

Per proposed new § 455.418, each State would have to submit to CMS on a monthly basis – and in a format required by CMS -- the legal business and doing business names, address, tax identification number, and National Provider Identifier of each Medicaid or CHIP provider that, within the applicable monthly period, the State: (1) denied or terminated under § 455.416; or (2) was required to deny or terminate under § 455.416 but declined to do so because the State

determined that a denial or termination was not in Medicaid's best interests. As part of this, the State must cite the regulatory basis involved, the facts of the case, and an explanation (with, as applicable, supporting rationale) for its decision.

Including all States and territories (hereafter collectively "States"), there are 56 Medicaid programs in the United States. The time it would take for each State to submit its report would vary by State and month (for example, larger States may have more denials and terminations to disclose). Strictly to establish an estimate, we project that the average hour burden for each report would be 1.5 hours. Concerning costs, we estimate that the data would be prepared and submitted to CMS by one State Medicaid official with an hourly wage equivalent to that of a GS-9, Step 5 Federal employee in the Washington, D.C./Baltimore/Arlington payment locality, or $38.35.[213] The figure is $76.70 with FBO. The consequent annual ICR burden would be 1,008 hours (56 programs x 12 reports/program x 1.5 hours/program) with a $77,314 cost (1,008 hours x $76.70/hour).

h. Reporting COIs Within 30 Days

Under our existing regulations, certain changes in Medicare enrollment information must be reported within 30 calendar days of the change while others must be disclosed within 90 days. As earlier indicated, we are proposing a standard 30-day timeframe for all such changes. As with past Medicare provider enrollment rulemaking where we have reduced submission timeframes to 30 days for certain changed data, we do not believe this regulatory revision would increase the currently approved ICR burden of COI submissions. This is because COIs must still be submitted irrespective of whether a 30-day or 90-day deadline applies.

i. Total Projected Burden

Table C-A23 outlines the estimated annual hour and cost ICR burdens of our provider enrollment proposals.

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213 https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2026/DCB_h.pdf

TABLE C-A23: ANNUAL ICR BURDEN OF PROPOSED PROVIDER ENROLLMENT PROVISIONS OVER 3-YEAR PERIOD

Provision/Requirement	OMB Number	Number of Respondents	Number of Responses	Burden per Response (Hours)	Total Annual Burden (Hours)	Hourly Wage (Includes Fringe Benefits and Overhead) ($)	Total Cost
Form CMS-855S Initial Enrollments (Including Changes in Majority Ownership that Require a New Enrollment) – Disclosing Additional Parties (§ 424.57(i))	0938-1056	5,167	5,167	0.67	3,462	46.80	$162,022
Form CMS-855S Reactivations - Disclosing Additional Parties (§ 424.57(i))	0938-1056	5,176	5,176	0.67	3,468	46.80	$162,302
Form CMS-855S Revalidations - Disclosing Additional Parties (§ 424.57(i))	0938-1056	17,413	17,413	0.67	11,667	46.80	$546,016
Form CMS-855S Changes of Information - Disclosing Additional Parties (§ 424.57(i))	0938-1056	2,500	2,500	1	2,500	Varies	$175,578
Documentation Verifying Identity and Other Information (§ 424.510(d))	0938-New	1,000	1,000	0.25	250	46.80	$11,700
State Reports on Medicaid & CHIP Denials and Terminations (§ 455.418)	0938-New	56	672	1.5	1,008	76.70	$77,314
MA Enrollment Requirements (Forms CMS-855A, CMS-855B, CMS-855I, and CMS-855S)*		Varies	Varies	Varies	151,887	Varies	$11,080,585
TOTALS	**N/A**	**31,312**	**31,928**	**Varies**	**174,242**	**Varies**	**$12,215,517**

* See Table C-A23 – Hour and Cost Estimates in First 3 Years of MA Enrollment Requirement for more information.

Per Table C-A23, we project in each of the first 3 years of our proposed provider enrollment requirements an average annual ICR burden of 174,242 hours and $12,215,517.

5. Marketplace Program Integrity

a. Strengthening Oversight of Agents, Brokers, and Web-brokers in the Marketplace

This rule proposes a number of additions and amendments to 45 CFR 155.20 and § 155.220 to improve the integrity of the Federally-facilitated Exchanges (FFEs) and State-based Exchanges on the Federal platform (SBE-FPs), reduce abusive conduct by agents, brokers, and

web-brokers, and better protect consumers within the FFEs and SBE-FPs. We are proposing to amend § 155.20 to add definitions of "convicted" and "credible allegation of abusive conduct." We are also proposing to add participation standards for agents and brokers to § 155.220(g)(3), which would prevent agents and brokers that pose an undue risk from participating in the FFE. Additionally, we are proposing to amend § 155.220(g)(5) to increase transparency around program integrity oversight of the FFEs and SBE-FPs and further strengthen our administrative actions against suspected bad actors and amend § 155.220(j)(2)(i) and (ii) by adding specific examples of behavior that CMS considers abusive conduct.

To further strengthen oversight and improve the fairness of enforcement proceedings following findings of agent, broker, and web-broker noncompliance as defined in § 155.220(g)(2), we are proposing additional revisions to § 155.220. Specifically, to increase transparency and to help ensure accuracy and efficiency in CMS noncompliance determinations and resulting enforcement actions, we propose to amend § 155.220(g)(3)(i) to replace the existing opportunity for agents, brokers, and web-brokers to "resolve" noncompliance determinations before CMS terminates their Exchange Agreements(s) Exchange agreement(s) and imposes other penalties with an opportunity to "refute." We also propose to codify factors that CMS would consider when determining whether to terminate an agent, broker, or web-broker's Exchange agreement(s) for cause and to impose other penalties under § 155.220(k)(1) after making a noncompliance determination. In addition, we propose to amend § 155.220(h) to clarify that agents, brokers, or web-brokers may request reconsideration when HHS denies them the right to enter into Exchange agreement(s) in addition to when CMS terminates their Exchange agreement(s) for cause.

We also propose to add a new standard in § 155.220(j) to codify a term in the existing Exchange Agreements, requiring agents, brokers, and web-brokers to implement and maintain reasonable safeguards to ensure that access and attempted access to the FFEs and SBE-FPs, systems that support the FFEs and SBE-FPs, and personally identifiable information obtained

through the FFEs and SBE-FPs occur only from locations within the United States.

We do not believe that the proposed changes to § 155.20 and § 155.220 would impose any new collection of information requirements. Agents, brokers, and web-brokers may be asked to submit documentation over the course of a noncompliance or abusive conduct investigation and enforcement action, as well as for potential referral for nonprocurement suspension and debarment. However, CMS believes these changes would be exempt from the PRA requirements as stated in 5 CFR 1320.4(a)(2), because the collection would occur during the conduct of an investigation and/or administrative action. The proposed changes to §§ 155.20 and 155.220 are not subject to the requirements of the PRA.

6. ICRs Relating to Clarification of Existing Unsolicited Beneficiary Contact Requirement and Adding a New Unsolicited Beneficiary Contact Prohibition (42 CFR 424.57(c)(11) and (c)(31))

In section VIII. of this proposed rule, we propose to clarify the existing prohibition against unsolicited beneficiary contact by DMEPOS suppliers at 42 CFR 424.57(c)(11) to make explicit the inclusion of third-party entities acting as the agents of DMEPOS suppliers; and to clarify that the prohibition against unsolicited beneficiary contact by telephone refers to a telephone call or message, including text messages. In addition, we propose to add a new supplier standard under 42 CFR 424.57(c)(31) to prohibit unsolicited beneficiary contact by DMEPOS suppliers and their agents when supplying a Medicare-covered item by direct messages from social media platforms, email message without opt-out features, and door-to-door in-person solicitation, unless a specified exception applies.

While there is burden associated with complying with this standard, we believe it is exempt from the PRA as stated in 5 CFR 1320.3(b)(2), to the extent that the time, effort, and financial resources necessary to comply with the information collection requirements would be incurred by DMEPOS suppliers in the normal course of their activities.

DMEPOS suppliers have been prohibited from engaging in unsolicited beneficiary contact by telephone when supplying a Medicare-covered item for decades. The current

regulation (42 CFR 424.57(c)(11)) requires the DMEPOS supplier to obtain written permission from the beneficiary to allow telephone contact, or, in the alternative, that the DMEPOS supplier has furnished a Medicare-covered item to a beneficiary and is coordinating delivery or has furnished a covered item to the beneficiary during the 15-month period preceding the date of contact. Further, CMS' and HHS-OIG's interpretation of the current provisions already prohibits a DMEPOS supplier's agents from engaging in unsolicited telephone calls to beneficiaries. Given the existing requirements, DMEPOS suppliers typically maintain such policies and records as a usual and customary business practice.

We solicit comments on our proposed provisions, burden estimates, and assumptions.

C. Summary of Collection of Information Burden and Savings Estimates for Proposed Requirements

TABLE C-A24: SUMMARY OF PROPOSED COLLECTION OF INFORMATION BURDEN ESTIMATES (IN MILLIONS)

Policy Area	Associated Burden Estimates
Medicaid and CHIP Program Integrity ICR Cost Savings to States	($69.75)
Medicare Advantage and Medicare Part D Program Integrity ICR Costs	$274.23
Provider Enrollment Program Integrity ICR Costs	$122.20
Marketplace Program Integrity ICR Costs	N/A
Clarifying Existing Requirement and Adding a New Unsolicited Beneficiary Contact Provision ICR Costs	N/A
Total Associated Burden Estimate	**$326.68**

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed previously, please visit the CMS website at https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing, or call the Reports Clearance Office at 410-786-1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES**

and **ADDRESSES** sections of this proposed rule and identify the rule (CMS-6098-F, RIN 0938-AV97), the ICR's CFR citation, and the OMB control number.

IX. Regulatory Impact Analysis

A. Statement of Need

CMS' current Original Medicare, Medicaid and CHIP, Medicare Advantage, Medicare Part D, and Marketplace program integrity frameworks contain outdated, inconsistent, or incomplete requirements across several regulatory areas. These gaps limit CMS' ability to detect fraud, hold States accountable, and recover improper payments. The proposals below address these gaps by modernizing reporting, clarifying enforcement authority, and closing structural vulnerabilities in oversight tools. CMS seeks public comments on all assumptions and estimates related to stakeholders impacted, benefits, costs, and transfers as part of these provisions.

1. Medicaid and CHIP Program Integrity

a. PERM CAPs (§§ 431.992(a), (b)(3)(ii)(E), (b)(3)(ii)(F), (c), and (e) and 431.1010(b)(2)(ii))

Section 431.992 currently requires each State selected for a Payment Error Rate Measurement (PERM) review to develop separate Medicaid and Children's Health Insurance Program (CHIP) corrective action plans (CAPs) for each improper payment rate measurement. Each CAP must address the State's PERM errors and deficiencies and include an error analysis, corrective actions, an implementation schedule and monitoring plan, and an evaluation of the CAP from the previous measurement. States must submit and begin implementing the CAP no later than 90 calendar days after their improper payment rates are posted and must provide implementation updates annually and upon request. A State with an eligibility improper payment rate above 3 percent for consecutive PERM years must also submit implementation updates every other month.

Although the existing requirements provide an important framework for addressing PERM errors and deficiencies, the current process requires each State to prepare and submit two CAPs—one for Medicaid and one for CHIP—even when the two submissions include similar information. The every-other-month update requirement also results in six responses each year for affected States. In addition, CMS currently reviews State CAPs and requests revisions when

a submission does not sufficiently address the applicable requirements, but § 431.992 does not expressly set out an approval, revision, and disapproval process.

To reduce duplicative administrative work and clarify the CAP process, we propose to revise § 431.992(a) to require one combined Medicaid and CHIP PERM CAP while preserving the separate program requirements through program-specific identification of each error, deficiency, and CAP element. We also propose to revise § 431.992(b)(3)(ii)(E) and add § 431.992(b)(3)(ii)(F) to clarify the monitoring and effectiveness-evaluation information included in the CAP; establish at § 431.992(c) a CMS approval, revision, and disapproval process with a defined 90-calendar-day correction period; and revise § 431.992(e) to reduce eligibility corrective action implementation updates from every other month to every 6 months. Under proposed § 455.804, implementation of a CMS-approved Medicaid PERM CAP would be a condition for approval of a good faith waiver of an eligibility-related disallowance, but would not require a separate submission.

b. Medicaid and CHIP Managed Care Oversight Policies

States generally pay Medicaid managed care plans a per member per month capitation payment to provide a specified benefit package. These payments are made for Medicaid-eligible enrollees regardless of whether an enrollee uses services in a given month. Under § 438.3(c)(2), managed care plans may retain capitation payments only for Medicaid-eligible enrollees. States also must ensure that capitation rates are actuarially sound and reflect the reasonable, appropriate, and attainable costs of providing services under the contract, as required by § 438.4(a).

Existing requirements provide a foundation for preventing payments on behalf of individuals who are no longer eligible, but they do not fully address how changes in an enrollee's circumstances are reported and how resulting capitation overpayments are recovered. Section 438.608(a)(3) requires managed care plans to promptly notify the State when they receive information about changes in an enrollee's circumstances that may affect an enrollee's

eligibility, including a change of address or death. The regulation does not define "prompt" or require states to specify procedures for receiving these reports. As a result, states and plans may learn of or act on changes at different times. An out-of-state move or death may go unreported while capitation payments continue, and an in-state move may leave an enrollee assigned to a plan whose service area no longer includes the enrollee's residence.

Federal oversight has demonstrated the financial significance of these gaps. A Department of Health and Human Services Office of Inspector General (HHS-OIG) review found that Medicaid incurred approximately $117.1 million in capitation costs in August 2020 associated with beneficiaries concurrently enrolled in managed care programs in two states. Separate HHS-OIG audits of 14 states identified more than $249 million in unallowable capitation payments made on behalf of deceased enrollees, including $172 million in Federal funds. CMS has also identified practical barriers to recovery, including uncertainty about the date of an out-of-state relocation and managed care contracts that do not clearly address recovery of the associated payments.

Limited State access to data and the current regulatory ambiguity create a need for clearer, more consistent requirements that allow states to identify these changes, determine their effect on eligibility and plan enrollment, and recover inappropriate capitation payments. To address this need, we propose to amend § 438.608(a)(3) to require managed care plans and PCCMs to report an enrollee's death and verified address changes within 30 calendar days of receiving the information, and to require states to establish procedures for those reports. We also propose to amend § 438.3(c)(2) to clarify the recovery of capitation payments for periods following an enrollee's death or out-of-state relocation and the return of the applicable Federal share to CMS. These recovery actions would occur between states and managed care plans and would not create liability for beneficiaries. Applicable eligibility redetermination, notice, and fair hearing requirements would continue to govern state action affecting an enrollee's coverage.

Finally, we propose to clarify § 438.608(d)(1)(iv) so that the overpayment return

flexibilities in § 438.608(d) do not result in duplicative treatment of recoveries retained under the False Claims Act or through other Federal or State investigations. Together, these revisions would strengthen Medicaid and CHIP managed care program integrity, improve the accuracy of capitation payments, and give states and plans clearer procedures for reporting and addressing changes in enrollee circumstances.

c. Revisions to 455.17 Reporting Requirements

States are currently required to report certain provider fraud and abuse information to CMS pursuant to 42 CFR 455.17. These reporting requirements were established in 1983 and designed primarily to capture basic information regarding provider fraud and abuse investigations. The authority to collect this information expired in 1986. While these reporting requirements may have provided useful information to CMS and its oversight partners, they have not been updated to reflect significant changes in law and regulatory landscape. They were, for example, developed decades before the 2006 enactment of the Medicaid Integrity Program at section 1936 of the Act which significantly bolstered our development of nationwide Medicaid program integrity efforts and before the widespread use of modern data analytics, cross-State information sharing, managed care program integrity activities, and many current fraud detection techniques.

Under the expired requirements at § 455.17(a), States were required to report to CMS the number of fraud and abuse complaints that warranted a full investigation. Under § 455.17(b), for cases of suspected provider fraud and abuse that warranted a full investigation, States are required to report: (1) the provider's name and number; (2) the source of the complaint; (3) the type of provider; (4) the nature of the complaint; (5) the approximate range of dollars involved; and (6) the legal and administrative disposition of the case, including actions taken by law enforcement. Consistent with the 1983 final rule (48 FR 3756), these reporting requirements applied only to suspected provider fraud and abuse cases and did not extend to suspected beneficiary fraud cases.

These requirements were meant to provide a foundation for Medicaid program integrity reporting for over 40 years, but CMS has determined that they no longer provide the level of detail necessary to support effective national oversight or provide CMS with sufficient information to hold States accountable for lacking program integrity operations. Specifically, the expired existing reporting requirements do not consistently provide information necessary to support national trend analysis, identify emerging fraud schemes, evaluate investigative outcomes, or coordinate oversight activities among Federal and State partners. CMS, State Medicaid Agencies (SMAs), Medicaid Fraud Control Units (MFCUs), Unified Program Integrity Contractors (UPICs), managed care plans, and law enforcement entities routinely coordinate activities involving provider investigations and administrative actions, and more detailed and standardized reporting would meaningfully strengthen those efforts.

We have also identified specific data gaps in the prior reporting requirement that limited its usefulness for program integrity purposes. The prior reporting requirement did not consistently capture provider identifiers in a standardized format, limiting CMS' ability to cross-reference reported cases against other data sources or match investigation records across States and programs. It also did not capture the estimated or final overpayment amounts associated with investigated cases, limiting CMS' ability to evaluate the financial impact of fraud and abuse activity or assess the effectiveness of State investigative efforts. Finally, the prior reporting requirement did not capture administrative actions taken by SMAs (such as provider terminations, payment suspensions, and overpayment recovery actions) separately from law enforcement dispositions, limiting CMS' visibility into the full range of program integrity actions States are taking in response to identified fraud and abuse.

To address these issues, we propose to revise § 455.17 to modernize Medicaid fraud and abuse reporting requirements and improve the usefulness of information reported to CMS. Consistent with the prior scope of § 455.17, these proposed revisions would apply only to suspected provider fraud and abuse cases and would not extend reporting requirements to

beneficiary cases. Specifically, we propose to amend § 455.17(b) to require States to report the following additional data elements for cases of suspected provider fraud and abuse that warranted a full investigation: (1) the provider's NPI, or Medicaid ID if the provider is ineligible to receive a NPI; (2) the provider's Employer Identification Number or Taxpayer Identification Number (EIN/TIN); (3) the State in which the investigation is being conducted; (4) the investigation status; (5) the type of service involved; (6) the payor (for example, Fee-For-Service, managed care); (7) the relevant claim dates; (8) the estimated overpayment amount; and (9) where available, the final overpayment amount and the approximate time period covered by the investigation. We also propose to renumber the existing § 455.17 (and expand is scope to include additional reporting options to include the disposition of the case to include administrative actions taken by the SMA, including provider termination, payment suspension (including good cause exceptions identified under § 455.23), and overpayment recovery status, in addition to the existing requirement to report actions taken by law enforcement.

We seek comments on these proposals, including on the operational feasibility of the proposed data elements, whether additional data elements should be included, and the timeframe States would need to come into compliance with the revised reporting requirements.

d. Medicaid Payment Suspensions Updates (§ 455.23)

This set of proposed provisions would impact all 50 States, the District of Columbia, and the applicable territories. Including all States and territories (hereafter collectively “States”), there are 56 Medicaid programs in the United States.

Consistent with sections 1902(a)(68) of the Act (which requires States to require certain entities to maintain policies and procedures for detecting fraud, waste, and abuse) and 1903(i)(2)(C) of the Act (which prohibits payment of Federal Financial Participation (FFP) with respect to services furnished by a provider to which the state has failed to suspend payment pending investigation of a credible allegation of fraud (CAF)), we are proposing a number of

Medicaid payment suspension provisions to strengthen and clarify certain aspects of the payment suspension process.

Medicaid is one of the largest Federal-state partnership programs in the United States. Fraud, waste, and abuse represent a persistent threat to the program's financial integrity. Payment suspensions based on CAFs are among the most powerful tools available to State Medicaid Agencies (SMAs) to halt potentially fraudulent payments before they become unrecoverable, while the CAF is investigated. The proposed regulatory changes are designed to ensure that this tool is used consistently, effectively, and in a timely manner across all States. Medicaid and CHIP fraud undermine the programs' integrity and harm the public. Fraudulent providers exploit gaps in oversight to extract payments from a public insurance program funded by Federal and State taxpayers. The costs are borne broadly by the public, while the benefits accrue to bad actors. The payment suspension provisions described address this failure in distinct and complementary ways.

TABLE C-B1: SUMMARY OF PROPOSED MEDICAID PAYMENT SUSPENSION REGULATORY CHANGES

Provision	Current Requirement	Proposed Change
§ 455.23(a)(1)(i)	SMAs must independently determine CAF credibility	SMAs may rely on CAF determinations by CMS or other Federal/State agencies
§ 455.23(d)(4)	Suspension must end if law enforcement declines referral	Suspension may continue if CAF remains under active investigation, regardless of whether law enforcement declines; quarterly redetermination required
§ 455.23(e)(1)(i)	Good cause exception invocable without case-specific verification	SMAs must verify good cause exception on a case-by-case basis and report basis to CMS
§ 455.23(g)(3)	Annual reporting of payment suspension activity	Quarterly reporting; removal of "summary" qualifier

(1) Inconsistent State Implementation of CAF Determinations

Under the current regulatory framework, the absence of explicit guidance on whether SMAs must independently redetermine the credibility of a CAF received from an outside agency has produced significant variation in State practice. Some States immediately initiate payment

suspensions upon receipt of an externally determined CAF, while others conduct full independent credibility reviews before acting. This inconsistency creates exploitable gaps: bad actors operating in States with more deliberate review processes may continue receiving Medicaid payments for extended periods, increasing the total overpayment amount and reducing the likelihood of full recoupment.

The financial consequences of delayed payment suspensions are compounded by the behavior of fraudulent providers once detected. Upon discovery, such providers frequently cease operations, dissolve business entities, or file for bankruptcy protection, leaving States with limited or no viable pathway to recover funds already disbursed.

(2) Payment Suspension Lapses Due to Law Enforcement Declinations

CMS has observed that payment suspensions may be terminated because MFCUs or other law enforcement agencies have declined fraud referrals due to resource constraints or competing priorities. Under current § 455.23(d)(4), States without alternative Federal or State authority to maintain the suspension are required to terminate it upon law enforcement declination, even when the CAF remains credible and unresolved. This creates a structural vulnerability in the payment suspension framework that is unrelated to the merits of the underlying allegation.

(3) Overutilization of Good Cause Exceptions

CMS data (reported by states) from CY 2025 indicates that approximately 75 percent of CAF cases reported under § 455.23(g)(3) did not proceed to a payment suspension because an SMA invoked a good cause exception. Several States reported good cause exception rates exceeding 90 percent, with some States recording hundreds of good cause exceptions against only a handful of actual payment suspensions. While good cause exceptions serve a legitimate purpose — particularly when a payment suspension could compromise an active law enforcement investigation — the data suggests that some States may be invoking the exception as a blanket policy to avoid provider abrasion, administrative burden, or litigation risk, rather than on a case-by-case basis as required.

(4) Limitations of Annual Reporting

The current annual reporting cadence under § 455.23(g)(3) limits CMS' ability to identify emerging trends, provide timely technical assistance to States, and conduct effective program integrity oversight. Given that much of the relevant data is already exchanged between SMAs and MFCUs on a quarterly basis through existing case tracking systems, the annual reporting requirement represents a missed opportunity for more proactive and responsive oversight.

e. National Provider Identifier (NPI) Requirements for Medicaid Providers (§ 455.440)

Accurate provider identification is fundamental to the effective administration of the Medicaid program and to CMS' ability to oversee program integrity activities. Provider identifiers support virtually every operational component of Medicaid administration, including provider enrollment, claims processing, payment administration, managed care oversight, fraud detection, audit activities, and coordination with Federal and State oversight partners. As Medicaid programs have become increasingly dependent upon electronic data exchange and sophisticated analytical tools, consistent provider identification has become an essential component of effective program administration.

The Department adopted the National Provider Identifier (NPI) as the standard unique health care provider identifier under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Administrative Simplification provisions. Since its implementation, the NPI has become the nationally recognized provider identifier used throughout Medicare and much of the commercial health care sector. The NPI was specifically designed to improve administrative efficiency by providing a single identifier that could be used consistently across multiple health care transactions and operational systems.

Within Medicaid, however, provider identification practices have evolved incrementally over time rather than through the implementation of a comprehensive enterprise-wide provider identification strategy. Although States generally collect NPIs where required for HIPAA standard transactions or specific Medicaid operational functions, current Medicaid regulations do

not require States to consistently collect, maintain, and use NPIs throughout all systems for every Medicaid provider eligible to obtain an NPI.

As a result, States have developed differing approaches to provider identification. In many States, multiple provider identifiers continue to exist across separate business functions, with internal provider numbers serving as the primary identifier for some operational activities while NPIs are used only where specifically required. Consequently, the same provider may be represented by different identifiers within provider enrollment systems, claims processing systems, managed care oversight activities, program integrity databases, and reporting systems.

CMS has determined that inconsistent provider identification practices have become an increasingly significant limitation on effective Medicaid program integrity oversight. Over the past decade, CMS has substantially expanded the use of advanced data analytics, predictive modeling, and coordinated Federal and State oversight activities. The effectiveness of these activities depends upon accurate and consistent provider identification.

When provider identifiers differ across operational systems or jurisdictions, CMS' ability to accurately associate provider activity across multiple datasets is diminished. These inconsistencies reduce the effectiveness of automated data matching, increase administrative complexity, and require additional manual review before investigative resources can be effectively deployed.

CMS has also identified specific operational limitations associated with inconsistent provider identifiers that affect several complementary proposals contained elsewhere in this proposed rule. For example, elsewhere in this proposed rule CMS proposes to strengthen State reporting requirements under § 455.17 by requiring additional standardized information regarding provider fraud and abuse investigations. The usefulness of those additional reporting elements depends in significant part upon the availability of a standardized provider identifier.

CMS believes that these considerations collectively demonstrate that existing Medicaid regulations no longer provide sufficient consistency to support modern Medicaid program

integrity operations.

f. Requirements for Program Integrity Corrective Action Plans (§ 455.600, *et seq.*)

Effective oversight of Medicaid and CHIP requires that CMS have mechanisms to ensure States address identified vulnerabilities. Despite ongoing efforts to provide effective oversight, we continue to find errors and deficiencies in State program integrity operations that result in repeat findings and recommendations. Currently, our authority to take action for instances of sustained non-compliance with Federal requirements is limited to a small subset of CMS program integrity initiatives. Our ability to require a State to develop and implement a Corrective Action Plan (CAP) in response to our program integrity-related activities is significantly limited.

As a result of these limitations, our existing authorities do not sufficiently allow us to take administrative actions should a State fail to effectuate their CAPs or comply with program integrity requirements. This significantly limits the effectiveness of our oversight efforts and allows known vulnerabilities to persist.

To address these gaps, we propose to amend part 455 by adding a new subpart G (§ 455.600, et seq.) titled "Requirements for Program Integrity Corrective Action Plans" that codifies the administrative actions we may pursue when States fail to comply with program integrity requirements. Specifically, we propose adding a new § 455.602 that would require a State to respond to a final audit report by developing and implementing a Program Integrity CAP for each area of non-compliance. The necessary elements of the Program Integrity CAP would be codified in new § 455.602(b) and serve as a basis for CMS to evaluate whether the Program Integrity CAP mitigates program integrity risks in a meaningful and effective way.

g. Medicaid and CHIP Beneficiary Eligibility Audits (§ 455.700, *et seq*.)

This rule proposes to establish a Medicaid and CHIP beneficiary eligibility audit program under new part 455, subpart H (§ 455.700, et seq). The Medicaid and CHIP beneficiary eligibility audits provide us with enhanced oversight of States' eligibility determination

processes, enable us to focus additional resources on high-risk States, and strengthen our ability to identify and recover erroneous excess payments. By establishing a regulatory framework for our beneficiary eligibility audits, we intend to increase transparency of audit requirements and procedures. If this rule is finalized as proposed, future audit findings could result in disallowances under section 1903(u) of the Act, establishing a new mechanism for overpayment recovery. In addition, beneficiary eligibility audits will be conducted more frequently, with each State undergoing an audit at least once in a five-year period and some States audited multiple times within that period based on their risk score.

h. Enhanced Electronic Visit Verification (EVV) Requirements

Section 1903(l) of the Act requires the use of EVV systems for certain services provided by an in-home provider. However, there are no existing Federal regulations establishing how EVV data must be used by SMAs. This rule proposes to amend §§ 455.14 and 447.45(f) to require SMAs to use collected EVV data for specific program integrity and improper payment oversight activities. We propose to amend § 455.14 to require that SMAs incorporate a review of EVV records as part of preliminary investigations into potential Medicaid fraud or abuse involving in-home service providers subject to Federal and State EVV requirements. We also propose to amend § 447.45 to require that SMAs verify that billed services are supported by EVV records during prepayment claims review, where applicable under Federal or State requirements.

2. Medicare Advantage and Medicare Part D Program Integrity

a. Mandatory Reporting of Fraud, Waste, and Abuse (42 CFR 422.500, 422.503 and 423.504)

All Medicare Advantage (MA) organizations and Part D plan sponsors are required to adopt and implement effective compliance programs to oversee provider networks, benefits, and payments. Compliance programs must include measures that prevent, detect, and correct non-compliance with CMS' program requirements, including fraud, waste, and abuse.[214] As part of

[214] *See* section 1860D-4(c)(1)(D) of the Act and 42 CFR 422.503(b)(4)(vi) and 423.504(b)(4)(vi).

these requirements, plan sponsors must establish and implement procedures and systems for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensuring ongoing compliance with CMS requirements.

An important part of plan sponsors' fraud, waste, and abuse initiatives involves sharing data with CMS. In accordance with the requirements of Sections 2008 and 6063 of the SUPPORT Act, CMS established a secure web-based program integrity portal for plan sponsor reporting in the HPMS FWA Reporting Module in the Contract Year 2022 Medicare Advantage and Part D Final Rule (CMS-4190-F2) (86 FR 5864). Since January 1, 2022, under §§ 422.503(b)(4)(vi)(G)(*4*)-(*5*) and 423.504(b)(4)(vi)(G)(*4*)-(*5*) and the associated timelines for reporting found at §§ 422.503(b)(4)(vi)(G)(*6*) and 423.504(b)(4)(vi)(G)(*6*), plan sponsors must report to CMS: (1) payment suspensions pending investigations of credible allegations of fraud by pharmacies; and (2) information concerning investigations, credible evidence of suspicious activities of a provider (including a prescriber) or supplier related to the inappropriate prescribing of opioids, and other actions taken by the plan sponsor related to the inappropriate prescribing of opioids. In addition, when plan sponsors choose to report a referral of substantiated or suspicious activities of a provider or supplier related to fraud, waste, or abuse, they must also use the HPMS FWA Reporting Module to do so in accordance with §§ 422.503(b)(4)(vi)(G)(*5*) and 423.504(b)(4)(vi)(G)(*5*).

In this proposed rule, CMS proposes to expand on its implementation of the requirements in Sections 2008 and 6063 of the SUPPORT Act. Specifically, CMS is proposing to require the reporting of a referral of substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste and abuse to initiate or assist with investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners as well as require the reporting of all payment suspensions based on

credible allegations of fraud for all providers and suppliers, rather than only those by pharmacies.

CMS believes that increased reporting is essential to the oversight of the Medicare Part C and Part D programs, as this information is valuable to CMS and assists with investigations, referrals to law enforcement, and trend monitoring. In addition, more stringent reporting requirements allow CMS to anonymously share more robust data on referred providers or suppliers with other MA organizations and Part D contracts on a quarterly basis to assist in their own internal fraud, waste, and abuse efforts. Data transparency and information sharing with our partners are at the core of CMS' strategy to crush fraud. Changes proposed in this rule will affect the Medicare Part C and Part D plan sponsors contracted with CMS to provide Medicare beneficiaries coverage under the Medicare Part C and Part D programs.

b. Risk Adjustment Data Validation (RADV)

This rule proposes certain program integrity policies in the MA program, specifically, the recovery of improper payments identified during RADV audits, and aligns with the Administration's focus on the fiscal sustainability of the MA program and the interests of Medicare beneficiaries, providers, and MA organizations. Additionally, this rule proposes a hardship exception request process for MA organizations facing extraordinary circumstances and unable to comply with contract-specific RADV audit requirements.

The improper payment measurements conducted each year by CMS, which are included in the HHS Agency Financial Report, as well as audits conducted by the HHS-OIG, have demonstrated that the MA program is at high risk of improper payments. In FY 2025 (based on CY 2023 payments), we calculated that CMS made over $21 billion in Part C overpayments.[215] The HHS-OIG has also released several reports over the past few years that also demonstrate a

[215] HHS, FY 2025 HHS Agency Financial Report, pg. 154, https://www.hhs.gov/sites/default/files/fy-2025-hhs-agency-financial-report.pdf. CMS made over $23 billion in total Part C improper payments. The improper payment measurement for the MA program in FY 2025 included both overpayments ($21 billion) and underpayments ($2 billion).

high risk of improper risk adjustment payments in the MA program,[216] and has identified the MA program as one of the top management and performance challenges facing HHS for several years

[216] https://oig.hhs.gov/reports/all/2026/cms-potentially-overpaid-medicare-advantage-organizations-462-million-based-on-certain-unsupported-acute-stroke-diagnosis-codes/https://oig.hhs.gov/reports/all/2026/medicare-advantage-compliance-audit-of-specific-diagnosis-codes-that-priority-health-contract-h2320-submitted-to-cms/https://oig.hhs.gov/reports/all/2026/medicare-advantage-compliance-audit-of-specific-diagnosis-codes-that-gateway-health-plan-inc-contract-h5932-submitted-to-cms/https://oig.hhs.gov/reports/all/2026/medicare-advantage-compliance-audit-of-specific-diagnosis-codes-that-blue-cross-and-blue-shield-of-alabama-contract-h0104-submitted-to-cms/https://oig.hhs.gov/reports/all/2025/medicare-advantage-compliance-audit-of-specific-diagnosis-codes-humana-health-benefit-of-louisiana-contract-h1951-submitted-to-cms/https://oig.hhs.gov/reports/all/2025/medicare-advantage-compliance-audit-of-specific-diagnosis-codes-that-coventry-health-and-life-insurance-company-contract-h1608-submitted-to-cms/https://oig.hhs.gov/oas/reports/region7/71901187.asphttps://oig.hhs.gov/oas/reports/region2/21801028.asphttps://oig.hhs.gov/oas/reports/region3/31900001.asphttps://oig.hhs.gov/oas/reports/region2/22001009.asphttps://oig.hhs.gov/oas/reports/region7/71701169.asphttps://oig.hhs.gov/oas/reports/region7/71601165.asp For example, see reports: CMS Potentially Overpaid Medicare Advantage Organizations $462 Million Based on Certain Unsupported Acute Stroke Diagnosis Codes, Issued on May 28, 2026, https://oig.hhs.gov/reports/all/2026/cms-potentially-overpaid-medicare-advantage-organizations-462-million-based-on-certain-unsupported-acute-stroke-diagnosis-codes/;
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Priority Health (Contract H2320) Submitted to CMS, Issued March 31, 2026,
https://oig.hhs.gov/reports/all/2026/medicare-advantage-compliance-audit-of-specific-diagnosis-codes-that-priority-health-contract-h2320-submitted-to-cms/;
Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Gateway Health Plan, Inc., (Contract H5932) Submitted to CMS, Issued March 12, 2026,

https://oig.hhs.gov/reports/all/2026/medicare-advantage-compliance-audit-of-specific-diagnosis-codes-that-gateway-health-plan-inc-contract-h5932-submitted-to-cms/;

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Blue Cross and Blue Shield of Alabama (Contract H0104) Submitted to CMS, Issued March 10, 2026,

https://oig.hhs.gov/reports/all/2026/medicare-advantage-compliance-audit-of-specific-diagnosis-codes-that-blue-cross-and-blue-shield-of-alabama-contract-h0104-submitted-to-cms/;

Medicare Advantage Compliance Audit of Specific Diagnosis Codes Humana Health Benefit of Louisiana (Contract H1951) Submitted to CMS, Issued December 18, 2025,

https://oig.hhs.gov/reports/all/2025/medicare-advantage-compliance-audit-of-specific-diagnosis-codes-humana-health-benefit-of-louisiana-contract-h1951-submitted-to-cms/;

Medicare Advantage Compliance Audit of Specific Diagnosis Codes That Coventry Health and Life Insurance Company (Contract H1608) Submitted to CMS, Issued June 3, 2025,

https://oig.hhs.gov/reports/all/2025/medicare-advantage-compliance-audit-of-specific-diagnosis-codes-that-coventry-health-and-life-insurance-company-contract-h1608-submitted-to-cms/.

due to the high rate of improper payments.[217] The Medicare program, including MA, has also been identified by the GAO as a high-risk program due to the risk of substantial improper payments.[218]

RADV audits are CMS's main corrective action for improper overpayments in the MA program made to MA organizations when there is a lack of documentation in the medical record to support the diagnoses reported for risk adjustment. The RADV audits confirm the presence of the diagnoses related to the enrollee's HCC profile through the review of certain categories of medical records submitted by the MA organizations for the purpose of a RADV audit. Risk adjustment discrepancies are identified when an enrollee's HCCs used for payment (which is, again, based on MA organization self-reported data) differ from the HCCs assigned based on the medical record review performed by CMS through the RADV audit process. Risk adjustment discrepancies can be aggregated to determine an overall amount of payment error for sampled enrollees. In turn, this payment error for the sample of contract enrollees can be extrapolated to calculate a payment error estimate for the universe of enrollees from which the sample is selected.

The provisions in this proposed rule are essential to having an effective RADV program that protects taxpayer dollars and ensures oversight of the MA program.

3. Medicare Provider Enrollment Provisions

Consistent with section 1866(j) of the Act, we are proposing several Medicare provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. These include, but are not limited to, adding and modifying grounds for denying or

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[217] https://oig.hhs.gov/reports-and-publications/top-challenges/2021/2021-tmc.pdf For example, see OIG, 2024 Top Management and Performance Challenges Facing HHS, https://oig.hhs.gov/reports-and-publications/top-challenges/2021/2021-tmc.pdf https://oig.hhs.gov/documents/tmc/10057/2024%20Top%20Management%20and%20Performance%20Challenges%20Facing%20HHS.pdf

[218] https://www.gao.gov/highrisk/medicare-program-improper-payments For example, see reports: GAO, *Medicare Program & Improper Payments,* https://www.gao.gov/highrisk/medicare-program-improper-payments; *Actions Needed to Reduce Improper Payment and Fraud Risks in VA Community Care and Medicare Advantage*, GAO-26-107946 (2026), https://www.gao.gov/products/gao-26-107946.

revoking a provider's or supplier's Medicare enrollment. We are also proposing to enhance our DMEPOS supplier surety bond process under § 424.57(d), to collect additional information from DMEPOS suppliers regarding certain relationships they may have, and to require DMEPOS suppliers to have a process for obtaining prior DMEPOS beneficiary consent for items the supplier sends to the beneficiary at their home or residence. We are further proposing to revise subparts B and E of 42 CFR Part 455, which address Medicaid and CHIP provider enrollment, to: (1) add more reasons for which the State must deny or terminate a provider's enrollment; and (2) require Medicaid and CHIP providers to submit certain data regarding their ownership, management, and associated adverse legal history. Too, we are proposing that providers that bill MA for services and items furnished to MA beneficiaries be enrolled in Original Medicare in order to receive payment. All the foregoing changes are necessary to help ensure that payments are made only to qualified Medicare, Medicaid, CHIP, and MA providers and suppliers, that the Medicare program can recoup monies it is owed, and that the financial integrity and beneficiaries of Medicare, Medicaid, CHIP, and MA are protected.

4. Marketplace Program Integrity

In recent years, there has been a substantial increase in consumer complaints from individuals who reported they were unaware they had been enrolled by an agent, broker, or web-broker in Exchange coverage. From 2023 through 2025, CMS received over 624,000 consumer complaints attesting to unauthorized Exchange enrollments or unauthorized plan switching by agents, brokers, or web-brokers and confirmed by issuer and CMS review; 300,000 of the 624,000 were received in 2025 alone. These improper enrollments may constitute abusive conduct, costing Federal taxpayers billions of dollars and can cause significant medical or financial harm to consumers.

Consistent with sections 1312(e), 1313, and 1321 of the Affordable Care Act (ACA), we are proposing a number of additions and amendments to 45 CFR 155.220 to improve the integrity of the FFEs, reduce abusive conduct by agents, brokers, and web-brokers, and better

protect consumers within the FFEs. These proposals include but are not limited to: (1) amending 45 CFR 155.20 to add a definition of "convicted" and "credible allegation of abusive conduct,"(2) adding participation standards for agents and brokers to 45 CFR 155.220(g)(3), which would prevent agents and brokers that pose unacceptable risk from participating in the FFE, (3) amending 155.220(g) to replace the existing 30-calendar day opportunity to resolve noncompliance before CMS may terminate an agent, broker, or web-broker's Exchange agreement(s) for cause with an opportunity to refute identified noncompliance and to codify factors that CMS would consider in determining whether to terminate an agent, broker, or web-broker's Exchange agreement(s) for cause and to impose other penalties, (4) amending 45 CFR 155.220(g)(5) to increase transparency around program integrity oversight of the FFE and further strengthen our administrative actions against suspected bad actors, (5) amending 45 CFR 155.220(j)(2)(i) and (ii) by adding specific examples of behavior that CMS considers abusive conduct, and (6) codifying a term in the existing Exchange Agreements with the FFEs and SBE-FPs which would prohibit agents, brokers, and web-brokers from accessing and attempting to access, the FFEs and SBE-FPs, Exchange systems, and personally identifiable information obtained through the FFEs and SBE-FPs from outside the United States. The impacted stakeholders for the provisions described in this section are agents, brokers, and web-brokers participating in the FFEs and SBE-FPs, and their downstream entities such as employees of agents, brokers, and web-brokers, contractors engaged by agents, brokers, and web-brokers, and subcontractors engaged by those contractors.

5. Clarifying Existing Requirement and Adding a New Unsolicited Beneficiary Contact Prohibition

This rule includes a provision to clarify the existing prohibition against unsolicited beneficiary contact by DMEPOS suppliers to make explicit the inclusion of third-party entities acting as the agents of DMEPOS suppliers; and to clarify that the prohibition against unsolicited beneficiary contact by telephone refers to a telephone call or message, including text messages.

This rule also includes a provision to add a new supplier standard under 42 CFR 424.57(c)(31) to prohibit unsolicited beneficiary contact by DMEPOS suppliers and their agents when supplying a Medicare covered item by direct messages from social media platforms, email messages without opt-out features, and door-to-door in-person solicitation, unless a specified exception applies.

Fraudulent billing for Medicare DMEPOS continues to be a major concern. Despite an existing prohibition on unsolicited beneficiary contact by telephone, DMEPOS suppliers and third parties acting as their agents are targeting Medicare beneficiaries with unsolicited text messages and other direct messages, door-to-door in person solicitation, unwanted telephone calls, and other means to engage in high-pressure marketing tactics and deceptive lead generation that allow DMEPOS suppliers to bill Medicare for medically unnecessary or unneeded items, or items that are never supplied at all. These changes are necessary to help ensure that legitimate DMEPOS suppliers are furnishing medically necessary items of DMEPOS to Medicare beneficiaries consistent with Medicare requirements, which we believe would assist in protecting the Trust Funds and Medicare beneficiaries.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866, "Regulatory Planning and Review"; Executive Order 13132, "Federalism"; Executive Order 13563, "Improving Regulation and Regulatory Review"; Executive Order 14192, "Unleashing Prosperity Through Deregulation"; the Regulatory Flexibility Act (RFA) (Pub. L. 96-354); section 1102(b) of the Social Security Act; and section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts.). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as any regulatory action that is likely to result in a

rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f) of E.O. 12866. The Office of Information and Regulatory Affairs has determined that this is a significant regulatory action per section 3(f).

We believe these proposed changes would meaningfully improve CMS' nationwide visibility into program integrity activities, facilitate trend analysis, improve coordination among Federal and State oversight entities, and support evaluation of program integrity outcomes. We also believe these enhanced reporting requirements would strengthen States' ability to meet their responsibilities relating to fraud and abuse reporting, oversight, and data analysis under section 1902(a)(64) of the Act. We also considered whether to expand the scope of § 455.17 reporting to include waste, in addition to fraud and abuse. We are not proposing to make that change at this time, as doing so would likely require corresponding revisions to the preliminary and full investigation requirements at §§ 455.14 and 455.15, and we want to carefully evaluate the State burden implications of such an expansion before proposing such a policy. However, we seek comments on whether and how waste should be incorporated into § 455.17 reporting requirements in future rulemaking, including what types of activities States would consider waste for reporting purposes and what burden such a requirement would impose on SMAs.

C. Detailed Economic Analysis

As was mentioned in the COI section of this rule, "To estimate the financial burden on States, it was important to consider the Federal Government's contribution to the cost of

administering the Medicaid and CHIP programs. The Medicaid FMAP that is established for each State is based on the per capita income in the State as compared to the national average. Medicaid FMAPs range from a minimum of 50 percent in States with higher per capita incomes to a maximum of 83 percent in States with lower per capita incomes, but exceptions to the regular FMAP rate exist for certain States, situations, populations, providers, and services. For Medicaid, all States generally receive a 50 percent FMAP for administration. States also receive higher Federal matching rates for certain systems improvements, redesign, or operations, including a 90 percent match rate for the design, development, and enhancement of Medicaid information technology (IT) systems. We have estimated that States would contribute 10 percent of applicable Medicaid IT costs. For CHIP, Congress created an "enhanced" Federal matching rate for CHIP that is generally about 15 percentage points higher than the Medicaid rate, averaging 71 percent nationally.

To determine the Federal contribution to the costs of administering the Medicaid and CHIP programs for purposes of estimating State burden with respect to the collections of information and reviewing the regulation and training staff, we elected to use the higher end estimate that the States would contribute 50 percent of the costs. This assumption represents the upper bound of potential State burden, recognizing that the actual share is often lower once enhanced Federal match rates are applied."

1. Medicaid and CHIP Program Integrity

a. PERM CAPs (§§ 431.992(a), (b)(3)(ii)(E), (b)(3)(ii)(F), (c), and (e) and 431.1010(b)(2)(ii))

(1) Stakeholders Impacted

All 50 States, the District of Columbia, and the applicable territories are subject to these reporting requirements. Including all States and Puerto Rico (hereafter collectively "States"), there are 52 Medicaid programs in the United States applicable to PERM CAPs.

(2) Benefits

In addition to the quantified cost savings mentioned below, we expect the proposal to

require submission of combined Medicaid and CHIP PERM CAPs to produce difficult-to-quantify benefits for States and CMS. A single submission would reduce duplication and fragmentation, improve the organization and usefulness of PERM CAP information, and allow related Medicaid and CHIP findings and corrective actions to be presented in a coordinated manner. The combined format would also provide a clearer basis for reviewing implementation schedules, monitoring activities, and evaluations of corrective action effectiveness. For States, the streamlined process would reduce the staff needed to prepare and process CAP submissions while preserving existing corrective action implementation, monitoring, and evaluating responsibilities. For CMS, the combined CAP would streamline receipt, tracking, review, feedback, and follow-up and provide a more complete view of the State's corrective action efforts. The combined format would preserve program-specific accountability because each Medicaid and CHIP error, deficiency, corrective action, and required CAP element would continue to be separately identified, as applicable. Accordingly, the proposal would improve coordination and administrative efficiency without merging or reducing the distinct requirements applicable to Medicaid and CHIP. Under the current baseline, the 17 States in an annual PERM cycle submit 34 CAPs and incur an estimated 1,020 burden hours annually. Requiring one combined Medicaid and CHIP PERM CAP would reduce annual State responses to 17 and annual burden to 510 hours, eliminating 17 responses and 510 burden hours each year. Using the wage information from the Bureau of Labor Statistics (BLS) for claims adjusters, examiners, and investigators (Code 13-1031) (https://data.bls.gov/oes/#/area/0000000/2025), we estimate a mean hourly rate of $38.69 with an adjusted labor rate of $77.38 per hour including fringe benefits and overhead costs. Therefore the estimated annual labor-cost savings would be $39,464. After application of the 50-percent Federal administrative match, we estimate annual savings of $19,732 to States and $19,732 as transfers to the Federal Government. These savings would result from eliminating one duplicative CAP submission for each State while continuing to require program-specific identification of Medicaid and CHIP errors, deficiencies, corrective

actions, and other required CAP elements.

Clarifying the monitoring and effectiveness-evaluation elements would provide a more structured basis for assessing implementation progress and whether corrective actions are reducing or preventing repeat errors. Formalizing the existing CMS review and revision process would also provide clearer expectations for States without creating a separate response.

(3) Costs

Under current § 431.992, States already incur costs to analyze PERM errors and deficiencies, develop and document corrective actions, establish implementation schedules and monitoring plans, evaluate the CAP from the previous measurement, and prepare any necessary revisions. For the 17 States in an annual PERM cycle, the current requirement to prepare separate Medicaid and CHIP CAPs is estimated to require 1,020 hours annually, or 60 hours per State. Using the wage information from the BLS for claims adjusters, examiners, and investigators (Code 13-1031) (https://data.bls.gov/oes/#/area/0000000/2025) we estimate an adjusted labor rate of $77.38 per hour including fringe benefits and overhead costs, the estimated annual labor cost is $78,928, or $4,643 per State. After adjusting for the 50-percent Federal administrative match, the estimated annual cost is $39,464 to States and $39,464 transfer cost to the Federal Government.

Under this proposal, States would include the same program-specific CAP elements in one combined submission estimated to require 510 hours annually or 30 hours per State. The annual labor cost would be $39,464, or $2,321 per State. After adjusting for the 50-percent Federal administrative match, the estimated annual cost would be $19,732 to States and $19,732 transfer cost to the Federal Government. The 30-hour estimate includes the time needed to develop and document the required CAP elements, provide monitoring and evaluating for effectiveness information, review CMS feedback, and make ordinary revisions and resubmissions. These estimates quantify the administrative labor associated with developing, documenting, reviewing, revising, and submitting the CAP. The specific actions a State selects to

correct its errors and deficiencies may differ based on the nature and complexity of the State's findings. States would continue to undertake corrective action implementation, monitoring, and evaluation under the existing PERM CAP framework. We do not anticipate that these proposed amendments would cause those activities to occur more extensively than they would in the absence of the amendments.

Accordingly, the costs of the underlying corrective action activities remain in the baseline, and we estimate no additional operational costs attributable to these amendments. The existing regulation already requires the identified CAP elements and implementation activities.

Reducing eligibility corrective action implementation updates to every 6 months would decrease reporting frequency from six to two responses per year for affected States. The longer interval would reduce reporting burden and allow additional time for States to implement corrective actions and evaluate progress before submitting an update.

The proposed change to § 431.992(e) would reduce annual responses from 102 to 34 and annual burden from 306 hours to 102 hours, a reduction of 68 responses and 204 hours. As was determined in the COI section of this proposed rule, using the wage information from the BLS for claims adjusters, examiners, and investigators (Code 13-1031) (https://data.bls.gov/oes/#/area/0000000/2025) we estimate an adjusted labor rate of $77.38 per hour including fringe benefits and overhead costs. Therefore, the estimated total annual labor-cost reduction would be $15,785. After application of the 50-percent Federal administrative match, we estimate annual State costs of $7,893 after the application of 50 percent FMAP, which will represent an equal transfer cost of $7,893 to the Federal Government. The proposal would not amend § 431.992(d); accordingly, the currently approved burden associated with annual and CMS-requested updates under paragraph (d) would remain unchanged.

In total, we estimate that the affected requirements would reduce annual responses from 136 to 51 and annual burden from 1,326 hours to 612 hours at a total annual cost of $47,357. This represents a net annual reduction of 85 responses and 714 hours, annual cost savings of

$55,249. Using the wage information from the BLS for claims adjusters, examiners, and investigators (Code 13-1031) (https://data.bls.gov/oes/#/area/0000000/2025), the total annual labor-cost reduction would be $55,249, shown in the COI section, Table C-A3. For ease of reference and projection purposes, Table C-B2 presents the State share of those costs and administrative cost savings from 2027 through 2036 in 2026 dollars. Because the costs and administrative cost savings are projected over 10 years, the total estimated costs exceed the annual amount shown in the collection of information section.

TABLE C-B2: 10 YEAR PROJECTED COSTS TO STATES OF AMENDING § 431.992 (IN 2026 DOLLARS)

State Impact	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Costs under Current Requirements	$51,303	$51,303	$51,303	$51,303	$51,303	$51,303	$51,303	$51,303	$51,303	$51,303	$513,030
State Share of Costs under Proposed Requirements	$23,678	$23,678	$23,678	$23,678	$23,678	$23,678	$23,678	$23,678	$23,678	$23,678	$236,780
State Share of Admin. Cost Savings	$27,626	$27,626	$27,626	$27,626	$27,626	$27,626	$27,626	$27,626	$27,626	$27,626	$276,260

(4) Transfers

As was mentioned above, the Medicaid and CHIP Program Integrity annual transfer costs to the Federal Government are $23,678.

b. Medicaid and CHIP Managed Care Oversight Policies

(1) Stakeholders Impacted

All 50 States, the District of Columbia, and the applicable territories are subject to this reporting requirement. Including all States and territories (hereafter collectively "States"), there are 56 Medicaid programs in the United States.

Managed care plans. The burden estimate covers approximately 828 plan entries: 629 Medicaid and 199 CHIP managed care organizations, prepaid inpatient health plans, and prepaid ambulatory health plans.

(2) Revisions to Standard Contract Requirements Relating to Capitation Payments Retention (§§ 438.3(c)(2), 438.608(a)(3), and 438.608(d)(1)(iv))

We propose to amend § 438.608(a)(3) to require Medicaid and CHIP managed care plans and PCCMs to report an enrollee's death and verified address changes to the State within 30 calendar days of receiving the information. We also propose to require States to establish procedures for receiving these reports. To estimate labor costs, we use May 2025 national mean hourly wages from the Bureau of Labor Statistics and add 100 percent of wages for fringe benefits and overhead. The resulting hourly costs are $90.36 for a business operations specialist, $101.12 for a computer programmer, $129.74 for a general and operations manager, $91.12 for an accountant, and $44.80 for a customer service representative. The adjustment for benefits and overhead is an estimating assumption; it is not part of the BLS wage data.

For this illustrative projection, we assume that 629 Medicaid and 199 CHIP managed care contracts would be affected. CMS historical burden estimates, section IV.B. of this proposed rule: Supports the historical counts of 629 Medicaid and 199 CHIP contracts and 44 Medicaid and 32 CHIP State programs. These counts require confirmation for this proposal; the

source uses 654 Medicaid contracts for certain program integrity requirements. We estimate that each contract would require a one-time expenditure of 8 hours of business operations work to revise reporting and recovery procedures, 8 hours of programming to establish or modify reporting processes, and 2 hours of management review. BLS May 2025 national occupational wage data: Supports the base hourly wages used in the calculations; it does not establish the overhead adjustment or workload hours. At $1,791.32 per contract, the estimated one-time plan cost would be approximately $1.48 million across 828 contracts.

- **Plan reporting and recovery process setup:** We estimate a one-time burden for 828 Medicaid and CHIP managed care contracts. For each contract, we assume 8 hours of business operations work, 8 hours of programming, and 2 hours of management review.

++ *Total hours:* 828 contracts × (8 business operations + 8 computer programing + 2 management review) hours = **14,904 hours**.

++ *Total cost:* 828 × [(8 × $90.36) + (8 × $101.12) + (2 × $129.74)] = **$1,483,212.96**.

++ Federal and State shares:* Assuming a 50 percent FMAP match applies to all estimated costs, the Federal share is $1,483,212.96 × 50% = $741,606.48, and the remaining State share is $741,606.48.

States would incur costs to revise contracts and reporting instructions and establish procedures for receiving information from plans. Assuming 44 Medicaid and 32 CHIP State programs, we estimate a one-time expenditure of 8 hours of business operations work, 8 hours of programming, 4 hours of management review, and 4 hours of accounting work per program. This yields an estimated one-time State administrative cost of $183,561 across 76 program estimates. The Medicaid and CHIP figures are program counts and do not represent 76 distinct States. For this analysis, we assume States bear 50 percent of State administrative costs and the Federal Government bears the remaining 50 percent.

- **State contract and reporting process setup:** We estimate a one-time burden across 76 Medicaid and CHIP State program estimates. For each program, we assume 8 hours of

business operations work, 8 hours of programming, 4 hours of management review, and 4 hours of accounting work. The 76 program estimates do not represent 76 distinct States.

++ *Total hours:* 76 programs × (8 + 8 + 4 + 4) hours = **1,824 hours**.

++ *Total cost:* 76 × [(8 × $90.36) + (8 × $101.12) + (4 × $129.74) + (4 × $91.12)] = **$183,561.28**.

++ *State and Federal shares:* Assuming each pays 50 percent of State administrative costs, $183,561.28 × 0.50 = **$91,780.64 each**.

● **Plan processing of reported changes:** For an illustrative annual volume of 100,000 reports, we assume a plan customer service representative spends 5 minutes, or 1/12 hour, processing each report.

++ *Total hours:* 100,000 reports × 1/12 hour = approximately **8,333 hours**.

++ *Total cost:* 100,000 × 1/12 hour × $44.80 = **$373,333.33 annually**.

● **State processing of reported changes:** We assume a State business operations specialist spends 10 minutes, or 1/6 hour, processing each of the same 100,000 reports.

++ *Total hours:* 100,000 reports × 1/6 hour = approximately **16,667 hours**.

++ *Total cost:* 100,000 × 1/6 hour × $90.36 = **$1,506,000 annually**.

++ *State and Federal shares:* Assuming each pays 50 percent of State administrative costs, $1,506,000 × 0.50 = **$753,000 each annually**.

Combined burden: One-time setup totals **16,728 hours and $1,666,774.24** across plans and State programs. In the illustrative 100,000-report annual scenario, processing totals **25,000 hours and $1,879,333.33**, or approximately **$18.79 per report** across the plan and State activities. The annual figure excludes process maintenance. Actual annual costs depend on the number of additional reports attributable to the proposal.

TABLE C-B3: SUMMARY OF PROPOSED BURDEN ASSOCIATED WITH MANAGED CARE REPORTING AND CAPITATION RECOVERY REQUIREMENTS

Requirement	No. of respondents	Total responses	Frequency	Time per response (hr)	Total time (hr)	Wage ($/hr)	Total cost ($)	State cost ($)	Federal cost ($)

Plan reporting and recovery process setup	28 contracts	828	One-time	18	14,904	99.52*	1,483,212.96	—	—
State contract and reporting process setup	76 State program estimates	76	One-time	24	1,824	100.64*	183,561.28	91,780.64	91,780.64
One-time subtotal	**828 contracts; 76 program estimates**	**904**	**One-time**	**Varies**	**16,728**	**Varies**	**1,666,774.24**	**91,780.64**	**91,780.64**
Plan processing of reported changes	828 contracts	100,000 assumed reports	Annual scenario	0.0833	8,333	44.80	373,333.33	—	—
State processing of reported changes	76 State program estimates	100,000 assumed reports	Annual scenario	0.1667	16,667	90.36	1,506,000.00	753,000.00	753,000.00
Annual total with 100,000 reports	**828 contracts; 76 program estimates**	**100,000 reports processed by plans and States**	**Annual scenario**	**Varies**	**25,000**	**Varies**	**1,879,333.33**	**753,000.00**	**753,000.00**

* Note: The blended hourly rate reflects the occupational mix specified above. Costs were calculated using the individual occupational rates before rounding the blended rate shown in the table. The State and Federal columns divide State administrative costs equally under the assumed 50 percent sharing rate; they do not allocate managed care plans' labor costs. Displayed hours per report and total hours are rounded.

The table estimates $1.67 million in one-time setup costs. Of the State portion of those costs, States and the Federal Government would each bear approximately $91,781 under the assumed sharing rate. After setup, the table includes costs only when a plan and State process a report. At the assumed processing times, each reported change adds approximately $18.79 in combined labor costs. An illustrative 100,000 reports annually would cost approximately $1.88 million, including $1.51 million in State processing costs shared equally by States and the Federal Government. We do not have a reliable estimate of how many reports would be attributable to this proposal beyond those already submitted under existing requirements. More complex eligibility reviews, disputed relocation dates, payment recoveries, and appeals could add costs beyond the amounts shown.

More timely reporting and clearer recovery provisions could prevent improper capitation payments and increase recoveries from managed care plans to States, with the applicable Federal share returned to CMS. HHS-OIG found approximately $117.1 million in Medicaid capitation

costs associated with concurrent enrollment in two States in August 2020. Separate audits of 14 States identified more than $249 million in unallowable capitation payments on behalf of deceased enrollees, including $172 million in Federal funds. These historical findings indicate the potential scale of improper payments but are not projected savings from the proposals: some payments may already be identified or recovered, and the proposals would not prevent every payment identified in the audits.

We also propose to clarify § 438.608(d)(1)(iv) concerning recoveries retained under the False Claims Act or through other Federal or State investigations. We do not anticipate a separately measurable transfer from this clarification. We seek comment and supporting data on current contract and reporting practices, the number of changes plans would report each year, the staff time needed to review them, the frequency and cost of disputed recoveries, and the value of capitation payments States already recover.

(3) Transfers

Federal Government would bear approximately a one-time transfer cost of $ 91,781 and, based on the illustrative 100,000 reports annually would cost approximately $753,000 in transfers. See Table C-B3 in section VIII. Collection of Information Requirements of this proposed rule for a detailed accounting of these provisions, copied from the COI section.

c. Revisions to 455.17 State Reporting Requirements

(1) Stakeholders Impacted

All 50 States, the District of Columbia, and the applicable territories are subject to this reporting requirement. Including all States and territories (hereafter collectively “States”), there are 56 Medicaid programs in the United States.

(2) Overview

The States would be responsible for complying with the revised reporting requirements. CMS would benefit from more complete information concerning State program integrity activities, including provider terminations, payment suspensions, and overpayment recovery.

This regulatory requirement would allow CMS to make better financial impact assessments related to fraud reporting and clearer visibility into administrative actions.

Existing requirements do not capture administrative actions in addition to law enforcement dispositions. The proposed revisions would require States to report the following:

- Provider terminations.
- Payment suspensions (including good cause exceptions under § 455.23).
- Overpayment recovery status.

This would give CMS full visibility into the complete range of program integrity actions taken by States. The requirement could also foster stronger coordination among partners.

The updates would meaningfully strengthen coordination among--

- CMS.
- SMAs.
- MFCUs.
- UPICs.
- Managed Care Plans.
- Law enforcement entities.

Finally, this will allow CMS alignment with modern tools and law.

The original requirements predate--

- The 2006 Medicaid Integrity Program (§ 1936 of the Act).
- Modern data analytics.
- Cross-State information sharing.
- Managed care program integrity activities.
- Current fraud detection techniques.

The updates would bring reporting requirements in line with today's program integrity landscape.

(3) Benefits

(a) Enhanced National Oversight

The existing requirements — established in 1983 — no longer provide sufficient detail for effective national oversight. The proposed updates would:

- Enable national trend analysis of fraud and abuse patterns.
- Help identify emerging fraud schemes more quickly.
- Allow CMS to better hold States accountable for their program integrity operations.

(b) Improved Data Standardization

Current reporting lacks standardized provider identifiers. The proposed additions would require:

- NPI (National Provider Identifier) or Medicaid ID.
- EIN/TIN (Employer Identification Number / Taxpayer Identification Number).

This would allow CMS to:

- Cross-reference reported cases against other data sources.
- Match investigation records across States and programs.

(4) Costs

Current reporting does not capture overpayment amounts. The proposed updates would require:

- Estimated overpayment amounts.
- Final overpayment amounts (where available).
- Approximate time period covered by the investigation.

This enables CMS to evaluate the financial impact of fraud and abuse and assess the effectiveness of State investigative efforts.

We estimate that it will take a State Medicaid agency official approximately 2.00 hours to compile and report the additional data elements for each qualifying case. This estimate reflects the fact that much of this information (for example, claim dates, payor, and estimated overpayment amount) is likely already maintained by the State as part of its existing

investigation and case management processes and would primarily require compilation and formatting for submission to CMS rather than new data collection. (65 cases annually x 52 States = 3,380 cases) (3,380 cases x 2.00 hours=6,760 hours) (6,760 hours x $129.74= $877,042.40). The estimated annual cost is $877,042.40 with $438,521.20 as the state share to account for the 50 percent Federal match.

To derive estimated cost, we used data from the U.S. Bureau of Labor Statistics' May 2025 Occupational Employment and Wages for the occupation, "General and Operations managers" (Occupation Code 11-1021). This estimate includes the hourly wage ($64.87) with fringe benefits and overhead costs calculated at 100 percent ($64.87) totaling $129.74 per hour. We calculated this using the mean average of 65 cases per annually.

(5) Transfers

The estimated annual cost to the Federal Government is ($877,042.40*2= $438,521,20)

d. Medicaid Payment Suspensions Updates (§ 455.23)

(1) Stakeholders Impacted

All 50 States, the District of Columbia, and the applicable territories are subject to this reporting requirement. Including all States and territories (hereafter collectively "States"), there are 56 Medicaid programs in the United States. Medicaid providers whose payments are subject to suspension would also be impacted by this provision.

(2) Benefits

- **§ 455.23(a)(1)(i) — Authorization to Rely on External CAF Determinations**

++ *Reduction in Duplicative Administrative Review.* By permitting SMAs to rely on CAF determinations made by CMS or other Federal agencies, this provision would eliminate the need for independent credibility determinations in cases where a Federal agency has already established the existence of a CAF. The permissive standard is intended to provide a clear, affirmative authorization for States to rely on external CAF determinations — removing any regulatory ambiguity that currently causes some States to question whether such reliance is

permissible — while preserving the flexibility for States to exercise independent judgment where warranted. This is expected to reduce the administrative burden on SMAs and accelerate the initiation of payment suspensions. Since the number of payment suspension varies by State and by year, there is not a reliable way to estimate amount of administrative burden this proposed provision would remove from States. We also would not want to prescribe a floor or ceiling to the number of payment suspensions that a state should do in any given timeframe. Additionally, fraud schemes shift and may require administrative actions (e.g., payment suspensions) and at other times large-scale enforcement actions. We therefore do not have the data to make assumptions or estimates.

++ *Faster Payment Suspensions and Reduced Overpayments.* Reducing the time between a CAF referral and the implementation of a payment suspension would directly limit the number of potential overpayments disbursed during the intervening period. The magnitude of this benefit is a function of the volume of CAF referrals received from external agencies and the average payment amounts involved. Even modest reductions in the delay between CAF determination and payment suspension initiation could yield significant savings at the program level. Similarly to what was discussed above, the amount of potential savings is based on expected overpayments resulting from unknown future fraud schemes and the difference between each States' investigative times including the difference between the current and future reliance on CAF determinations made by CMS or other agencies. Since CMS does not dictate State policy and we see the large variability, we cannot estimate the potential savings from decreased overpayments.

++ *Uniform National Standards.* Establishing a clear, uniform standard for how SMAs may treat externally determined CAFs would reduce the exploitable variation in State practice and create a more consistent national framework for Medicaid program integrity. This benefit is not expected to have measurable outcomes.

++ *Deterrence.* A more consistent and rapid payment suspension response to CAF determinations may deter fraudulent providers from targeting Medicaid programs in States that previously had more deliberate review processes. This benefit is not expected to have measurable outcomes.

- **§ 455.23(d)(4) — Maintaining Payment Suspensions**

++ *Prevention of Suspension Lapses Due to Law Enforcement Resource Constraints.* By permitting SMAs to maintain payment suspensions when a CAF remains under active investigation — regardless of whether law enforcement has accepted the referral — this provision would close a structural gap that currently allows fraudulent payments to resume solely because of law enforcement capacity limitations unrelated to the merits of the underlying allegation. This would provide policy norms across States.

++ *Protection of Medicaid Funds During Ongoing Investigations.* Maintaining payment suspensions throughout the duration of an active investigation would preserve the financial integrity of the Medicaid program and maximize the potential for recoupment of improperly paid funds. Since the number of payment suspension and resources available to law enforcement agencies varies by State, we cannot estimate how much may be saved by this proposal. We also would not want to prescribe a floor or ceiling to the number of payment suspensions that a state should do in any given timeframe, as discussed above.

++ *Preservation of State Flexibility.* The proposed provision would preserve State flexibility by allowing — rather than requiring — SMAs to maintain suspensions, while establishing clear procedural guardrails (written documentation and quarterly redetermination) to ensure that suspensions remain tethered to actual, ongoing investigations. This benefit is not expected to have measurable outcomes.

++ *Safeguard Against Indefinite Suspensions.* The quarterly redetermination requirement would ensure that payment suspensions maintained under this provision remain time-limited and subject to meaningful review, consistent with the statutory authority under

section 1903(i)(2)(C) of the Act. This would protect providers from open-ended suspensions in cases where the underlying investigation has effectively concluded. This is a benefit to providers that is not expected to have measurable outcomes.

- **§ 455.23(e)(1)(i) — Verifying Good Cause Exceptions**

++ *Reduction in Improper Good Cause Exception Invocations.* We expect that requiring SMAs to affirmatively verify, on a case-by-case basis, that a good cause exception is warranted for each individual CAF case would reduce the rate of improper or unsupported good cause exception invocations. Based on CY 2025 data showing a 75 percent good cause exception rate, even a modest reduction in improper invocations could result in a meaningful increase in the number of appropriate payment suspensions implemented, with corresponding reductions in fraudulent payments. Since the number of payment suspensions and how States have used the law enforcement good cause exception varies by State, we cannot estimate how much may be saved by this proposal. Similarly, we would not want to direct States to implement a certain number of payment suspensions, as discussed above.

++ *Improved Accountability and Transparency.* Requiring SMAs to document the basis for each good cause exception and transmit documentation to CMS would create an auditable record of good cause exception decisions, enabling CMS to identify patterns of potential overutilization and provide targeted technical assistance. This benefit is not expected to have measurable outcomes.

++ *Alignment with Existing MFCU Obligations.* This proposed verification requirement would be consistent with existing obligations under § 1007.9(h), which already contemplates MFCUs providing quarterly updates to SMAs regarding payment suspensions for each case. This policy alignment is a benefit that is not expected to have a measurable outcome. The marginal burden of providing case-specific good cause confirmations is therefore expected to be limited.

- **§ 455.23(g)(3) — Quarterly Reporting**

++ *Enhanced CMS Oversight Capabilities.* Quarterly reporting would enable CMS to

compile and analyze program-wide data on payment suspension activity on a more timely basis, identify systemic trends earlier, and potentially provide technical assistance to States before problematic patterns become entrenched. More granular and timely data on payment suspension activity would enhance CMS' ability to conduct risk-based State Program Integrity reviews and target oversight resources toward States with potential systemic deficiencies. Similarly, quarterly data would support more robust and timely aggregate reporting on Medicaid program integrity outcomes, consistent with CMS' broader commitment to transparency and accountability. More frequent reporting would also enable CMS to identify States that may benefit from technical assistance and provide guidance in a more timely manner, reducing the risk that problematic patterns persist unaddressed for extended periods. Since fraud schemes are variable and how States choose to utilize technical assistance is anticipated to vary, we cannot estimate how much may be saved by this proposal.

We request comments from States on our benefits assumptions for the Medicaid payment suspension provisions.

(3) Costs

- *§ 455.23(a)(1)(i) — Authorization to Rely on External CAF Determinations.* The primary cost associated with this provision is the one-time administrative cost of updating internal policies and procedures to reflect the new standard. We estimate that it will take a State Medicaid agency official approximately 10 hours to update the internal policies and procedures. This estimate assumes that a standard operating procedure will need to be updated and that two drafts of the section on how to verify a credible allegation of fraud will be completed and then reviewed and verified by a second-line manager. For this estimate, we assume that all 56 States and territories will need to update their procedures in some way. To calculate an estimated cost, we used data from the U.S. Bureau of Labor Statistics' May 2025 Occupational Employment and Wages for the occupation, "General and Operations managers" (Occupation Code 11-1021). This estimate includes the mean hourly wage ($64.87) with benefits and overhead costs calculated at

100 percent ($64.87) totaling $129.74 per hour.[219] (56 States x 10 hours = 560 hours) (560 hours x 129.74 = $72,654.40). The estimated one-time cost is $72,654.40, with $36,327.20 as the state share to account for the 50 percent Federal match. We request comments from States on our assumptions.

- *§ 455.23(d)(4) — Maintaining Payment Suspensions.* The primary new cost associated with this provision is the administrative burden of preparing and maintaining written documentation of:

  ++ The initial determination that a CAF remains under active investigation; and

  ++ Subsequent redeterminations conducted quarterly.

Using the U.S. Bureau of Labor Statistics' May 2025 Occupational Employment and Wages for the occupation, we assume that quarterly reporting would be completed by "Office and Administrative Support Workers, All Other" (Occupation Code 43-9199). The mean hourly wage for this position is $23.40 with benefits and overhead costs calculated at 100 percent ($23.40) totaling $46.80 per hour.[220] We estimate an average of 1.5 hours of work quarterly for a State to maintain one payment suspension (1.5 hours x 4 quarters = 6 hours) (6 hours x $46.80 = $280.80). We therefore estimate that the annual additional cost of a State to maintain one payment suspensions for 1 year with this provision is $280.80, with $140.40 as the state share to account for the 50 percent Federal match. Since we expect variation on how many payment suspensions are maintained within each State, we do not provide an annual estimate of cost to each State or as a whole. We request comments from States on our assumptions.

- *§ 455.23(e)(1)(i) — Verifying Good Cause Exceptions.* The primary new cost associated with this provision is the administrative burden of:

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219 https://data.bls.gov/oesprofile/?major_group=110000&occupation=111021&measure=01&areas=INDUSTRY,STATE,MSA.

220 https://data.bls.gov/oesprofile/?major_group=430000&occupation=439199&measure=01&areas=INDUSTRY,STATE,MSA.

++ Documenting the basis for the good cause exception; and

++ Transmitting the documentation to CMS.

Using the U.S. Bureau of Labor Statistics' May 2025 Occupational Employment and Wages for the occupation, we assume that quarterly reporting would be completed by "Office and Administrative Support Workers, All Other" (Occupation Code 43-9199). Using the U.S. Bureau of Labor Statistics' May 2025 Occupational Employment and Wages for the occupation, we assume that this work would be completed by "Office and Administrative Support Workers, All Other" (Occupation Code 43-9199). The mean hourly wage for this position is $23.40 with benefits and overhead costs calculated at 100 percent ($23.40) totaling $46.80 per hour.[221] We estimate 2 hours of work quarterly for a State to verify each good cause exception (2 hours x 4 quarters = 8 hours) (8 hours x $46.80 = $374.40). We therefore estimate that the annual additional cost of verifying each good cause exceptions with this provision is $374.40, with $187.20 as the state share to account for the 50 percent Federal match. To the extent that this provision reduces the number of improper good cause exception invocations, however, the above estimated burden may be partially offset by a reduction in the number of cases requiring good cause documentation. Since we expect variation on how many good cause exceptions are maintained within each State, we do not provide an annual estimate of costs to each State or as a whole.

MFCUs and other law enforcement agencies may also incur a marginal burden associated with providing case-specific good cause confirmations if they are not currently held to comply with § 1007.9(h). This burden is expected to be limited, given that MFCUs are already required under § 1007.9(h) to provide quarterly updates to SMAs regarding payment suspensions. We therefore only acknowledge this potential as opposed to adding the burden to this estimate. We

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221 https://data.bls.gov/oesprofile/?major_group=430000&occupation=439199&measure=01&areas=INDUSTRY,STATE,MSA.

request comments from States on our assumptions.

- *§ 455.23(g)(3) — Quarterly Reporting.* The primary new cost associated with this provision is the incremental administrative burden of compiling and submitting payment suspension data to CMS on a quarterly rather than annual basis. We estimate that the quarterly reporting requirement would require approximately 3 hours per quarter per State, depending on the volume of payment suspension activity. This cost is expected to be modest, given that much of the relevant data is already exchanged between SMAs and MFCUs on a quarterly basis through existing case tracking systems, and § 1007.9 already contemplates MFCUs transmitting payment suspension information to SMAs on a quarterly basis upon request.

Using the U.S. Bureau of Labor Statistics' May 2025 Occupational Employment and Wages for the occupation, we assume that quarterly reporting would be completed by "Office and Administrative Support Workers, All Other" (Occupation Code 43-9199). The mean hourly wage for this position is $23.40 with benefits and overhead costs calculated at 100 percent ($23.40) totaling $46.80 per hour.[222] We estimate 3 hours of work quarterly (56 States x 3 hours x 4 quarters = 672 hours) (672 hours x $46.80 = $31,449.60). We therefore estimate that the annual additional cost of quarterly reporting on payment suspension data with this provision is $31,449.60, with $15,724.80 as the state share to account for the 50 percent Federal match. We request comments from States on our assumptions.

See Table C-B3 for a summary of costs of proposed Medicaid payment suspension provisions. We request comments from States on our assumption.

TABLE C-B3: ANNUAL COSTS OF PROPOSED MEDICAID PAYMENT SUSPENSION PROVISIONS TO STATES

BURDEN TO STATE							
Provision	**Hour Burden Per Provision**	**Total Hours**	**Wage ($)**	**Total Cost**	**Total Average Annual Cost**	**Average Cost After 50% Federal Matching**	**Notes**

222 https://data.bls.gov/oesprofile/?major_group=430000&occupation=439199&measure=01&areas=INDUSTRY,STATE,MSA.

§ 455.23(a)(1)(i) — Authorization to Rely on External CAF Determinations - Update Policies	10	10	$129.74 per hour	$1,297.40	$72,654.40	$36,327.20	One time cost (2027 only)
§ 455.23(d)(4) — Maintaining Payment Suspensions	1.5	6 (1.5 x 4 quarters)	$46.80 per hour	$280.80	Variable	Variable	Total Cost is per payment suspension. Average Annual Cost will depend on the number of payment suspension per year
§ 455.23(e)(1)(i) — Verifying Good Cause Exceptions	2	6 (2 x 4 quarters)	$46.80 per hour	$374.40	Variable	Variable	Total Cost is per good cause exception. Average Annual Cost will depend on the number of good cause exception per year
§ 455.23(g)(3) — Quarterly Reporting	3	12 (3 x 4 quarters)	$46.80 per hour	$561.60	$31,449.60	$15,724.80	Annual recurring cost (2027 to 2036)

(4) Transfers

There are Federal transfer costs related to these proposed Medicaid payment suspension provisions due to the 50 percent administrative match that the Federal Government provides to States. For year 2027, there is a total Federal transfer cost paid to states of $52,052 (the $36,327.20 one-time cost for year 2027 only plus the $15,724.80 annual recurring cost, as shown in Table C-B3), and for each year from 2028 to 2036 the recurring annual Federal transfer cost paid to states is $15,724.80, as shown in Table C-B3. We also acknowledge that half of the total variable costs for maintaining payment suspensions and verifying good cost will be borne by the Federal Government as opposed to the States.

e. National Provider Identifier (NPI) Requirements for Medicaid Providers (§ 455.440)

(1) Stakeholders Impacted

The States and territories, and individual providers that act as Personal Care Attendants will be impacted by this provision. In the absence of comprehensive national data identifying the number and characteristics of all health care providers that would be newly affected by these requirements, this analysis uses personal care attendants (PCAs) as a proxy for estimating the potential burden on affected providers. PCAs provide a reasonable proxy because they represent a large population of individual providers participating in Medicaid-funded services for whom

provider identification, enrollment, and screening requirements vary across states. As a result, the PCA population provides an observable basis for estimating the administrative and financial burden associated with obtaining an NPI and completing related provider enrollment activities.

All 50 States, the District of Columbia, and the applicable territories are subject to this reporting requirement. Including all States and territories (hereafter collectively "States"), there are 56 Medicaid programs in the United States.

(2) Benefits

To address the limitations described above, this rule proposes to require State Medicaid agencies to collect, maintain, and use NPIs for all Medicaid providers eligible to obtain one. Under this proposal, the NPI would serve as the standardized provider identifier used consistently across Medicaid provider enrollment, claims processing, managed care oversight, program integrity, and reporting systems.

The proposed changes would improve the consistency and reliability of provider information available to States and CMS and strengthen the infrastructure supporting Medicaid program integrity activities. Although the proposed revisions would not directly prevent fraud or improper payments, the consistent use of NPIs would improve the ability of States and CMS to match provider information across Medicaid systems, identify potentially suspicious billing patterns, evaluate provider activity across jurisdictions, and coordinate program integrity and oversight activities.

The proposed benefits associated with this provision are primarily assessed qualitatively and include:

- **Improved Data Quality and Interoperability:** The proposed revisions would establish a standardized provider identifier across Medicaid systems, improving the consistency and reliability of provider information and facilitating more effective data matching. The use of a standardized identifier would also reduce administrative complexity associated with managing multiple maintaining and reconciling multiple provider identifiers.

- **Enhanced Program Integrity Analytics:** The proposed revisions would improve the ability of States and CMS to analyze provider information, identify potentially suspicious billing patterns, evaluate provider activity across jurisdictions, and support coordination of program integrity and investigative activities with other oversight entities.

- **Strengthened Foundation for Other Program Integrity Initiatives:** The standardized use of NPIs would provide infrastructure that supports other program integrity proposals in this rule, including enhanced fraud reporting under § 455.17 and EVV utilization requirements. More consistent provider identification would also provide a stronger foundation for existing and future Medicaid program integrity and oversight activities.

(3) Costs

As noted previously, this proposed rule would require State Medicaid agencies to collect, maintain, and use the NPI for all Medicaid providers eligible to obtain one. The proposed costs associated with this provision fall on the 10 State Medicaid agencies that do not currently require NPIs for PCAs. These 10 SMAs must update their systems and conduct provider outreach, and on certain individual providers who must newly obtain an NPI. The following cost estimates are derived from the approved Information Collection Request (OMB Control No. 0938-XXXX) associated with this provision.

- **State Medicaid Agency Burden:** We estimate a one-time implementation burden on the 10 State Medicaid agencies who do not currently require NPIs for PCAs, of 1,192.5 hours with an equivalent cost of $1,056,898. This is broken down into three activities:

- **Identification of Providers Lacking an NPI:** States will need to review their files to identify an estimated 1.28 million providers (primarily personal care attendants) who lack an NPI. We estimate this review will take one staff member 0.25 hours per State, performed by an Administrative Support Worker.

++ *Total Hours:* 10 Administrative Support Workers × 0.25 hr/provider = 2.5 hours

++ *Total Cost:* 2.5 hr × $46.80/hr = $117

- **System Updates for NPI Consistency:** States must update their Medicaid Enterprise Systems to ensure the NPI is used consistently across all modules. We estimate a one-time burden to be approximately 119 hours per State, for a total of 1,190 hours and a total cost of approximately $85,775 across 10 States.

- **Provider Outreach:** States will need to conduct outreach to providers who must obtain an NPI. We estimate a single, batched communication effort requiring 0.1 hours per staff member for 10 States, performed by an Administrative Support Worker.

++ *Total Hours:* 10 staff members × 0.1 hr/ x 1,280,000 providers = 128,000 hours

++ *Total Cost:* (128,000 hr divided by 10 States) × $46.80/hr = $599,040

- **Individual Provider Burden:** An estimated 1.28 million Medicaid providers will need to apply for an NPI through the National Plan and Provider Enumeration System (NPPES). The application is estimated to take 20 minutes (0.3333 hours) per provider.

++ This results in a total burden of 426,624 hours with an associated cost of $14,812,385. This burden is accounted for under the existing Paperwork Reduction Act approval for the NPI application (OMB Control No. 0938-0931) and is not a new cost attributable to this rule, but we present it here for a complete accounting of the rule's impact.

(4) Transfers

This provision does involve the direct transfers of funds because of the 50 percent Federal administrative match. This one-time transfer costs estimate is $1,056,898.

f. Requirements for Program Integrity Corrective Action Plans (§ 455.600, *et seq.*)

(1) Stakeholders Impacted

All 50 States, the District of Columbia, and the applicable territories would be subject to this reporting requirement. Including all States and territories (hereafter collectively “States”), there are 56 Medicaid programs in the United States. States would be responsible for complying with the correct action requirements, and CMS would oversee the resolution of audit findings.

(2) Benefits

We expect this proposal to generate meaningful benefits by systematizing the resolution of audit findings. By mandating a structured CAP process, CMS would be able to ensure that States take concrete, measurable steps to mitigate identified program integrity risks. This would reduce the incidence of repeat findings, strengthen overall program compliance, and safeguard Medicaid and CHIP funds more effectively.

(3) Costs

The costs associated with this provision would fall on State Medicaid agencies that are selected for a program integrity audit and subsequently required to submit a CAP. Based on our experience with existing PERM CAP requirements, we estimate that a State would require an average of 30 hours to develop a CAP for any given program integrity review or audit conducted by CMS that includes areas of Federal non-compliance.

We estimate 17 States would be selected no more than once each year for a program integrity audit. Assuming each of these 17 States would need to submit a program integrity CAP, we estimate an aggregate annual burden of 510 hours (17 States × 30 hours). Using an adjusted hourly wage of $77.38 for a claims adjuster, appraiser, examiner, and investigator, the total annual cost is estimated at $39,463.

(4) Transfers

This provision does involve the direct transfers of funds because of the 50 percent Federal administrative match. This annual transfer costs estimate is $19,732.

g. Medicaid and CHIP Beneficiary Eligibility Audits (§ 455.700, et seq.)

(1) Stakeholders Impacted

All 50 States and the District of Columbia would be subject to these requirements. States and CMS would be impacted by this provision. Sampled Medicaid and CHIP applicants and beneficiaries would potentially be impacted by this provision if an audit identifies that their most recent eligibility determination was incorrect.

(2) Benefits

The proposed changes to part 455 would codify the Medicaid and CHIP beneficiary eligibility audit program. The proposed eligibility audits would evaluate whether SMAs are determining Medicaid and CHIP eligibility in accordance with Federal requirements and claiming the appropriate Federal reimbursement. During these audits we would provide States with technical assistance to prospectively improve the accuracy of eligibility determinations. Should this rule be finalized as proposed, the eligibility audits would allow us to identify improper Medicaid and CHIP denials and terminations, as each beneficiary eligibility audit would include four statistically valid samples: one sample of active Medicaid cases, one of active CHIP cases, one of negative Medicaid cases, and one of negative CHIP cases.[223] In addition, the proposed eligibility audit program should better enable us to hold States accountable for improper Medicaid and CHIP eligibility determinations by establishing a new recovery mechanism for identified eligibility overpayments.

(3) Costs

This proposed rule would establish new requirements for States undergoing a Medicaid and CHIP beneficiary eligibility audit. The estimated quantified costs for States are associated with information collection requirements, and those impacts are reflected in the COI section of this rule. We estimate the annual burden to be 481 hours for each audited State, or 7,215 hours annually across all 15 States. Factoring in a 50 percent Federal administrative match, the State share of the burden across all 15 States is estimated to be $235,418 annually. For additional details on the calculated State burden, see the COI section of this proposed rule. Since we currently plan to audit the same number of States annually, we expect the estimated State expenditures for the eligibility audits to remain consistent. The projected annual State expenditures, Federal expenditures, and total expenditures for the next 10 years are shown in

[223] Negative cases are defined as individuals who have been denied enrollment in or disenrolled from Medicaid.

Table C-B4. However, we note that the actual costs to States and the Federal Government may differ from these estimates.

TABLE C-B4: PROJECTED STATE AND FEDERAL EXPENDITURES FOR THE MEDICAID AND CHIP BENEFICIARY ELIGIBILITY AUDITS, FY 2027-2036 (EXPENDITURES IN 2026 DOLLARS)

Fiscal Year	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036
State Expenditures ($ millions)	0.24	0.24	0.24	0.24	0.24	0.24	0.24	0.24	0.24	0.24
Federal Expenditures ($ millions)	0.24	0.24	0.24	0.24	0.24	0.24	0.24	0.24	0.24	0.24
Total Expenditures ($ millions)	0.48	0.48	0.48	0.48	0.48	0.48	0.48	0.48	0.48	0.48

(4) Transfers

We expect the proposed beneficiary eligibility audits to result in transfers from both the Federal Government to the States, and the States to the Federal Government. States generally receive a 50 percent Federal administrative match for administering the Medicaid program and CHIP. We estimate that the Federal Government is covering the Federal share of States' audit-related activity expenditures (refer to the COI section of this rule for additional information). We would expect transfer from State governments to the Federal Government if audits identify eligibility-related overpayments that result in a program-wide error rate that exceeds the 3 percent allowable threshold, and the State does not qualify for a good faith waiver. We cannot accurately estimate the amount of potential transfers from the State government at this time, since we have not performed any beneficiary audits using the proposed audit methodology.

h. Electronic Visit Verification

(1) Stakeholders Impacted

All 50 States, the District of Columbia, and the applicable territories would be subject to the requirements to utilize EVV data for certain program integrity and improper payment oversight activities. Including all States and territories (hereafter collectively "States"), there are 56 Medicaid programs in the United States.

(2) Benefits

The proposed changes to §§ 455.14 and 447.45(f) would establish requirements for the use of EVV data for certain State program integrity and improper payment oversight activities. The proposed changes are intended to benefit States by enhancing preliminary investigations of suspect providers and prepayment review processes. Specifically, our proposal seeks to enhance State identification and oversight of fraudulent and abusive activities by in-home service providers.

(3) Costs

At this time, we lack available data on the potential financial impact our proposed EVV requirements will have on SMAs. We seek comments on the potential costs required for State to integrate EVV record review into preliminary investigation and prepayment claims review processes. We are particularly interested in comments regarding whether system upgrades would be necessary to implement these requirements and if applicable, the associated cost of upgrades.

(4) Transfers

If there are any costs to the States, we anticipate that the proposed EVV requirements would result in direct transfer of funds from the Federal Government because of the 50 percent Federal administrative match. However, at this time, we lack available data on the potential financial impact our proposed EVV requirements will have on SMAs.

2. Medicare Advantage and Medicare Part D Program Integrity

a. Stakeholders Impacted

Medicare Advantage (MA) organizations and Medicare Part D Plan Sponsors will be impacted by these provisions.

We were unable to determine the overall impact of requiring MA organizations and Part D plan sponsors to report payment suspensions based on credible allegations of fraud and substantiated or suspicious fraud, waste, and abuse for all provider and supplier types to CMS because we do not have adequate data to support an estimate of the potential costs and savings due to the variability in plan sponsors' own internal processes, organization structures, and sizes.

CMS requests public comments and suggestions on the potential costs and savings associated with this proposal. As plan sponsors currently are required to maintain compliance programs that meet CMS requirements, including measures to prevent, detect, and correct fraud, waste, and abuse, CMS believes that the impact of this proposal will be on the staff entering referrals within the HPMS FWA Reporting Module. CMS believes this impact to be minimal as the staff implementing these proposed requirements are already familiar with the HPMS FWA Reporting Module and the expectations CMS has for these referrals. CMS believes there may be savings generated through actions taken by MA organizations and Part D plan sponsors that conduct their own due diligence based on the reporting and sharing of administrative actions, as well as through the use of leads generated in the FWA quarterly report. These activities include information sharing between CMS, MA organizations and Medicare Part D plan sponsors (including MA organizations offering MA-PD plans), as well as additional law enforcement actions. However, we cannot estimate the impact at this time given the variability in plan sponsors' internal processes, organization structure, and sizes. We welcome comments and suggestions for data that could be relied upon for this purpose.

MA organizations with contracts subject to Risk Adjustment Data Validation (RADV) audits and the Federal Government, through CMS, would be impacted by these provisions. MA organizations would be subject to recovery of improper payments based on extrapolated audit findings, with recovered funds transferred to the Federal Government. CMS would be responsible for the costs of administering the RADV audit program. The extrapolation provision would not increase MA organizations' audit compliance costs. The hardship exception provision would clarify existing policies for MA organizations experiencing extraordinary circumstances that prevent timely submission of medical record documentation.

b. Regulatory Review Costs for MA Organizations and PDPs

There are approximately 968 MA contracts (of which, 48 MA contracts include PDPs). We assume each entity will have one designated staff member who will review the entire rule,

clarify uncertainties, and disseminate the information to all the relevant decision makers within the organizations. Other assumptions are possible and will be reviewed after the calculations. Using the May 2025 wage information from the BLS for medical and health services managers (code 11–9111), we estimate that the cost of reviewing this rule is $135.54 per hour, including fringe benefits and overhead costs (https://data.bls.gov/oes/#/area/0000000/2025). Assuming an average reading speed for technical materials of 250 words per minute, we estimate that it will take approximately 1.5 hours for each person to review this final rule. For each entity that reviews the rule, the estimated cost is therefore $203.31 (1.5 hours * $135.54). Therefore, we estimate that the total cost of reviewing this regulation is $196,804.08 ($203.31 * 968 reviewers). Note that this analysis assumes one reader per contract.

c. Risk Adjustment Data Validation (RADV)

This proposed rule creates regulations to govern the collection of extrapolated audit findings in MA. As we develop our approach to statistical sampling and extrapolation, we are taking account of the recommendations of the 2016 GAO report[224] entitled, "Fundamental Improvements Needed in CMS' Effort to Recover Substantial Amounts of Improper Payments." The GAO recommended that CMS select plans based on the risk for improper payments. Prior to the GAO report, CMS selected stratified random samples of enrollees during RADV audits, including our 2011 to 2013 audits. However, beginning with audits of MA contracts for payment year 2014, CMS began incorporating the potential risk of improper payments to MA organizations, based on past audit findings and other factors, into selecting enrollee samples for audits. Accordingly, CMS expects to be more effective in identifying improper payments in future audit years.

To clarify in more detail how this proposed rule impacts the recovery audit process, we note the following:

[224] GAO, at 26, https://www.gao.gov/assets/gao-16-76.pdf (April 2016).

- The Part C Improper Payment Measurement program (not RADV audits) measures and reports improper payments in accordance with the Payment Integrity Information Act of 2019 (PIIA) Pub. L. (116-117) in the Medicare Part C program.[225] After defining the eligible population, a representative sample of beneficiaries from risk adjustment eligible contracts are selected for medical record review. MA organizations submit medical record documentation to substantiate the CMS-HCC payments sampled by CMS for each year's Part C Improper Payment Measurement. Certified coders code the medical records, and the findings are used to recalculate risk scores for each sampled beneficiary. The difference between the payment risk scores and the recalculated risk scores is termed Risk Adjustment Error. Validation results from the sample are extrapolated to the broader Part C population to produce payment error estimates that meet the PIIA requirements for the payment year. No recoveries are made through these audits.

- Findings from the Part C Improper Payment Measurement audits and contract-specific RADV audits are used to help identify cohorts of beneficiaries for which CMS may be most at risk for making improper payments to MA organizations. While CMS has flexibility to decide how to focus audits, starting with the PY 2014 audits, CMS took a more focused approach on areas of high risk of improper payments and CMS intends to focus audits on such MA organizations in the future and continue taking a more focused approach on areas of high risk of improper payments.

- By better targeting contract-specific RADV audits based on MA organizations' risk of receiving improper payments, CMS expects to have a sentinel effect and reduce the historical Part C improper payment rate over time.

- Lastly, CMS understands that there may be extraordinary circumstances beyond MA organizations' control that may make it difficult to meet medical record submission or other audit requirements. In this proposed rule, CMS is adding a provision to allow MA organizations

[225] See: https://www.cms.gov/data-research/monitoring-programs/improper-payment-measurement-programs/medicare-part-c-ipm for more information on the Medicare Part C Improper Payment Measurement

to request a hardship exception, as prescribed by CMS, if they cannot submit medical records timely as required. If CMS approves an MA organization's hardship exception request, the MA organization is not required to submit medical record documentation for the audited CMS-HCC and the audited CMS-HCC will not negatively impact error calculation.

d. Expected Impact of These Provisions

(1) Extrapolation

While we cannot fully estimate (quantitatively) the impact of this provision, we can clearly identify certain components of impact. We use the following facts and assumptions:

- Findings from audits of MA organization contracts for PYs 2011, 2012, 2013, 2014, and 2015 identified a total of approximately $37.6 million in improper payments (not extrapolated) for 29,900 sampled enrollees, and an average overpayment of $1,258 per sampled enrollee ($37.6 million divided by 29,900 sampled enrollees) transferred from the Federal Government to MA organizations. These improper payments resulted from human coding errors, which caused CMS to pay improper risk adjusted payments to MA organizations. We use the $37.6 million in improper payments and average overpayment per sampled enrollee from these audits to estimate future extrapolated recoveries (or transfers) for this proposed rule.

- As we are adopting GAO recommendations to focus on contracts at higher risk for improper payments, if we assume over the next ten-year period from 2027-2036 that the average overpayment per sampling frame enrollee in each RADV audit holds constant at $1,258, the total number of audited MA contracts is 8,260, and the total estimated number of sampling frame enrollees to be included in RADV audits is approximately 71.7 million, then the total estimated overpayments (with extrapolation) over the time period will be $90.2 billion (see Table C-B8).

We also assume the average number of MA contract audits concluded per calendar year and the average number of sampling frame enrollees associated with these audits per calendar year will be 826 and 7.2 million, respectively.

- Extrapolating audit findings does not increase the cost burden on an MA organization with an audited MA contract. The cost to the MA organization of complying with a RADV audit is neither the subject of nor affected by this provision.

- We estimate the total cost of the RADV audit program for the time period of 2027-2036 is approximately $478.7 million. This includes planned resources needed for support contracts, technology, and analytical tools/software needed to operate the program.

- We estimate that the annualized monetized cost of the contract-level RADV audit program for the time period of 2027-2036 is approximately $48 million.

In conclusion, with extrapolation applied to audit findings for payment years 2018 and later during calendar years 2027-2036, we estimate that the annualized monetized transfers from MA organizations to CMS would be approximately $9.2 billion and the annualized monetized cost would be $48 million for the contract-specific-RADV audit program.

In total, the estimated recovery amount from 2027 through 2036 is $90.2 billion; see Table C-B5. This money is a reduction in spending of the Medicare Trust Fund resulting mostly from recoveries, and this money is considered a transfer from MA organizations to the Federal Government; there will be no money transferred to enrollees.

The intent of this rule is to protect taxpayer dollars and ensure oversight of the MA program, in part, by reducing Part C improper payments.

TABLE C-B5: RADV TOTAL TRANSFER FROM MA ORGANIZATIONS TO THE FEDERAL GOVERNMENT WITH EXTRAPOLATION
($ IN MILLIONS)

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
RADV Audit ICR	$59.73	$22.39	$22.39	$22.39	$22.39	$22.39	$22.39	$22.39	$22.39	$22.39	$261.24
RADV Hardship Exception ICR	$0.47	$0.18	$0.18	$0.18	$0.18	$0.18	$0.18	$0.18	$0.18	$0.18	$2.09
RADV Transfer	$2,201.80	$16,804.20	$16,813.60	$13,586.70	$6,793.30	$6,793.30	$6,793.30	$6,793.30	$6,793.30	$6,793.30	$90,166.30

(2) Hardship Exception Request

We believe the proposed hardship request provision has no additional impact on MA organizations and is intended to clarify existing policies and processes. Submitting hardship exception requests for contract-specific RADV audits was previously in sub-regulatory guidance and benefits MA organizations to the extent they are able to demonstrate extraordinary circumstances that prevent them from submitting medical record documentation and complying with RADV audit requirements. We are seeking comments on documentation and process requirements.

TABLE C-B6: IMPACT ON ESTIMATED COLLECTIONS OF IMPROPER PAYMENTS PER YEAR FROM RADV PROVISIONS ($ IN MILLIONS)

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Estimated Non-Extrapolated Collections Assumed Without RADV Proposed Rule Changes	$18.0	$83.9	$85.3	$63.0	$31.5	$31.5	$31.5	$31.5	$31.5	$31.5	$439.1
Estimated Collections from Audits Completed with RADV Proposed Rule Changes	$2,201.8	$16,804.2	$16,813.6	$13,586.7	$6,793.3	$6,793.3	$6,793.3	$6,793.3	$6,793.3	$6,793.3	$90,166.3
Additional Estimated Collections as a Result of RADV Proposed Rule	$2,183.8	$16,720.4	$16,728.3	$13,523.7	$6,761.9	$6,761.9	$6,761.9	$6,761.9	$6,761.9	$6,761.9	$89,727.3

3. Provider Enrollment Program Integrity

a. Stakeholders Impacted

Medicare-enrolled providers and suppliers, including hospices, durable-medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers, and physicians, and other practitioners who order DMEPOS items or services, would be impacted by the proposed revocation provisions. Affected stakeholders also include hospice medical directors and administrators, as well as owners, managing employees, managing organizations, partners, officers, directors, and other individuals or entities whose relationships with providers or suppliers are addressed by these provisions. Additional affected parties include but are not limited to: (1) DMEPOS suppliers that would be required to report certain relationships; (2) providers that bill MA but are not enrolled in Medicare fee-for-service, who would now have to

enroll in order to receive MA payment; and (3) Medicaid and CHIP providers that would be required to report additional information under 42 CFR Part 424, subpart B, and be subject to denial and termination of their Medicaid and CHIP enrollment under § 455.416. The Federal Government (through CMS) and the States (for the Medicaid and CHIP provisions) would be responsible for administering and enforcing the proposed requirements.

b. Provider Enrollment

As previously noted, we are proposing a number of Medicare, Medicaid, CHIP, and MA provider enrollment provisions to strengthen and clarify certain aspects of the provider enrollment process. This RIA addresses provisions that: (1) we believe would have a financial impact; and (2) would not, in our view, have such an impact but which require explanation. For those that are not mentioned, we have determined that there would be no such impact -- though we note that certain provisions addressed in the ICR section of the proposed would have an ICR burden, which we have calculated in that section and will be included in the total cost estimate in this RIA.

(1) Medicare Provider Enrollment

(a) New Revocation Reasons

We are proposing the following new or expanded grounds for revoking Medicare enrollment:

- *Expanded § 424.535(a)(7)* - The provider or supplier engages in improper activity related to its Medicare enrollment, any billing number or identifier, or EFT arrangement.

- *New § 424.535(a)(26)* - The provider's or supplier's practice location is in the same suite or office as another provider or supplier whose Medicare enrollment has been revoked or denied under § 424.535 or § 424.530.

- *New § 424.535(a)(27)* - A hospice's enrollment may be revoked if any of the following apply:

++ The hospice's medical director is either of the following:

++ The medical director of multiple other hospices.

++ Practices at such a distance (for example, in a different State) from the enrolling hospice that the medical director cannot realistically perform all medical director functions required under 42 CFR part 418.

++ The hospice's administrator is either of the following:

++ The administrator of multiple other hospices.

++ Located at such a distance from the hospice that the administrator cannot realistically. perform all administrator functions required under 42 CFR part 418.

+ The hospice's medical director does not have an active physician medical license in the State in which they are practicing.

- *New § 424.535(a)(28)* - A hospice's enrollment may be revoked if the hospice changes its administrator within 36 months of its initial enrollment or its most recent change in administrator.

- *New § 424.535(a)(29)* - A physician's or practitioner's enrollment may be revoked if the individual ordered a DMEPOS item or service that was not reasonable or necessary.

- *New § 424.535(a)(30)* - The provider or supplier has a domestic or foreign owner, managing employee, managing organization, partner (general or limited), officer, or director:

++ Whose identity, location, or adverse action history cannot be confirmed; or

++ That CMS determines poses an undue risk of fraud, waste, or abuse to the Medicare program.

- *New § 424.535(a)(31)* – A DMEPOS supplier's enrollment may be revoked if CMS determines that any entity or individual reported pursuant to § 424.57(i) - or the relationship or business arrangement the entity or individual has with the supplier – poses an undue risk or fraud, waste, or abuse to the Medicare program or of beneficiary harm.

- *New § 424.535(a)(32)* – CMS determines that a revocation under § 424.536 (which would address certain provider changes in majority ownership) is warranted.

(i) Stakeholders Impacted

All Medicare providers and suppliers may be impacted by these provisions, though certain provisions only apply to certain provider and supplier types (such as hospices).

(ii) Benefits

As with all our prior provider enrollment revocation grounds, we believe our proposed revocation reasons would assist in protecting the Medicare program from non-compliant providers and suppliers, including those engaging in fraud, waste, or abuse.

(iii) Savings, Costs, and Transfers

As these are new or expanded revocation grounds, we have no historical data upon which we can base an estimate of savings, costs, or transfers. We thus request comments from stakeholders as to the potential impact.

(b) Potential Surety Bond Recoupment Amounts

We are proposing in new § 424.57(d)(16) that CMS may decline to accept from an authorized surety DMEPOS supplier surety bonds required under § 424.57(d) if the requirements of § 424.57(d)(16) (for example, providing the surety an opportunity to rebut CMS' intended declination) are met. We would also maintain a list of sureties from which CMS may decline to accept DMEPOS surety bonds under paragraph (d)(16).

(i) Stakeholders Impacted

Sureties and DMEPOS suppliers would be the principal parties impacted by this proposal.

(ii) Benefits

In section V. of this proposed rule, we cited data showing many millions of dollars in unpaid debts to CMS due to sureties' failures to make required payments under the bonds. We believe that proposed § 424.57(d)(16) would help spur sureties to fulfill their financial obligations to CMS.

(iii) Savings, Costs, and Transfers

Because this is a new provision, we have no historical information to assist us in projecting the amount of additional debts we would collect. In this same vein, we lack sufficient data to assess the impact to sureties under § 424.57(d)(16). We therefore seek comments from stakeholders, including sureties, as to (1) the potential additional recoupment from our surety bond proposal and (2) any other impacts associated with § 424.57(d)(16).

c. DMEPOS Accreditation Surveys

Under § 424.58, DMEPOS suppliers must be surveyed and accredited by a CMS-approved accrediting organization (AO): (1) to initially enroll in Medicare; and (2) on an annual basis to remain enrolled in Medicare; this includes, but is not limited to, accreditations for a new item type the supplier has not previously furnished or as required under the DMEPOS supplier CIMO provisions under § 424.551. We are proposing that an accreditation survey must also be performed if the supplier undergoes:

- A CIMO regardless of whether the change requires a new, initial enrollment under § 424.551.
- A change in practice location.

We made significant revisions to § 424.58's DMEPOS accreditation requirements in the CY 2026 HH PPS final rule (90 FR 55342). The aforementioned proposal expands upon these changes.

(1) Stakeholder Impact

The principal impacted stakeholders would be DMEPOS suppliers and DMEPOS AOs.

(2) Benefits

As explained in section V. of the proposed rule, we believe that our proposals would help ensure that the supplier under its new ownership or in its new location is compliant with the DMEPOS quality standards.

(3) Savings, Costs, and Transfers

Our proposal would involve two types of costs. One would be the cost to the supplier of the survey. While survey costs can vary widely by AO, we project a cost of roughly $3,000 per survey, which generally aligns with certain other survey cost estimates we made in the CY 2026 HH PPS final rule. The supplier would pay the survey fee to the AO. The second cost would involve the time and effort burden on the supplier and the AO in receiving and performing the survey. Consistent with various survey hour burden estimates we used in the CY 2026 HH PPS final rule, we will base our projections for our proposal on the following assumptions:

- It would take the AO 8 hours to perform the survey and 6 hours to review the results and make its determination.
- The supplier would incur a burden of 6 hours during the survey.
- The survey would be performed by AO personnel falling within the BLS wage category of "Other Healthcare Practitioners and Technical Occupations" (OHPTO) (Occupation Code 29-9000). The hourly mean wage is $35.55; the wage is $71.10 with fringe benefits and overhead.[226] https://data.bls.gov/oes/.
- Individuals in the BLS wage categories of "Registered Nurses" (Occupation Code 29-1141) and "Medical and Health Services Managers" (MHSM) (Occupation Code 11-9111) would review the survey results. The mean wage for registered nurses is $48.76 ($97.52 with fringe benefits and overhead costs and $67.77 for MHSMs ($135.54 with fringe benefits and overhead costs). As we did in the CY 2026 HH PPS final rule, we will combine these two hourly wages and then divide the total in half to derive an average fringe benefit and overhead wage for this activity, which would be $116.53 ($233.06/2).
- The BLS wage category for the supplier survey burden would be "Office and Administrative Support Workers, All Other" (Occupation Code 43-9199). The mean wage would be $23.40, or $46.80 with fringe benefits and overhead costs.

[226] https://data.bls.gov/oes/#/area/0000000/2025

Based on internal CMS data, we further project that approximately: (1) 500 suppliers per year would undergo a CIMO that would not require an initial enrollment; and (2) 851 suppliers per year would change their practice location.

With 1,351 (500 + 851) surveys being performed annually, the foregoing results in the following annual burden:

TABLE C-B7: ANNUAL COSTS AND TRANSFERS OF PROPOSED DMEPOS SUPPLIER SURVEY REQUIREMENTS

BURDEN TO AO				
Task	**Hour Burden Per Task**	**Total Hours**	**Wage ($)**	**Total Cost**
AO Burden – Survey	8	10,808 (8 x 1,351)	71.10	$768,449
AO Burden – Application/Post-Survey Review/Decision	6	8,106 (6 x 1,351)	116.53	$944,592
Accreditation Fee Collections	N/A	N/A	N/A	($4,053,000) (or $3,000 fee x 1,351 surveys)
TOTAL	14	18,914	Varies	($2,339.959)
BURDEN TO SUPPLIER				
Burden to Supplier During Survey	6	8,106 (6 x 1,351)	46.80	$379,361
Accreditation Fee	N/A	N/A	N/A	$4,053,000
TOTAL	6	8,106	N/A	$4,432,361
COMBINED NET BURDEN	**N./A**	**27,020**	**N/A**	**$2,092,402**

Note that the $4,053,000 in fee payments represents a transfer from DMEPOS suppliers to DMEPOS suppliers. The annual cost burden to the AOs would be $1,763,041 ($768,449 + $994,592) and that to DMEPOS suppliers would be $379,361. We have no historical data upon which we can estimate the amount of savings to Medicare based on the supplier's failure to meet the quality standards under these surveys, though we indeed expect savings.

d. Other DMEPOS Enrollment Proposals

As already mentioned in the ICR section of this proposed rule, two additional DMEPOS enrollment proposals are to--

- Collect additional information from DMEPOS suppliers on the Form CMS-855S regarding certain relationships they may have; and

- Require DMEPOS suppliers to have a process for obtaining prior DMEPOS beneficiary consent for items the supplier sends to the beneficiary at their home or residence.

(1) Stakeholders Impacted

DMEPOS suppliers and beneficiaries would be the parties most impacted by these proposals.

(2) Benefits

We explained at length in section V of this proposed rule that the aforementioned Form CMS-855S data collection would afford us valuable insight into the DMEPOS chain of

operations – a particularly important consideration in light of the DMEPOS fraud schemes we have seen. As for beneficiary consent, we also stated in section V. that this proposal could reduce the practice of beneficiaries receiving unwarranted or unnecessary items.

(3) Savings, Costs, and Transfers

For the former, we calculated in the ICR section of this proposed rule an annual reporting cost burden of $1,045,918 ($870,340 for initial, revalidation, and reactivation Form CMS-855S submissions + $175,578 for Form CMS-855S changes of information). Regarding the latter proposal, this requirement would involve the supplier e-mailing or telephoning the beneficiary or their representative for consent and recording the contact in a written log. We believe that some suppliers may already conduct this activity, in which case there would be no addition burden. However, to assist us in preparing a burden estimate, we request comments from stakeholders about: (1) the current prevalence of this activity among DMEPOS suppliers; (2) the typical time it would take a supplier to make and document the inquiry; and (3) how frequently within a certain time period (for example, one month) the supplier would have to undertake this task.

We believe there could be savings or transfers to the Medicare program from the revocation of DMEPOS suppliers that fail to comply with the beneficiary consent requirement or stemming from the Form CMS-855S reporting proposal. However, we have no historical enrollment data to help us assess a potential amount as these are new enrollment provisions.

e. Medicaid, CHIP, and MA Provider Enrollment and Other Considerations

(1) Additional Medicaid and CHIP Denial and Termination Reasons (§ 455.416)

We are proposing several new and expanded grounds for which the States must deny or terminate a provider's Medicaid or CHIP enrollment under § 455.416. These include, but are not limited to, the following:

- *Non-compliance:* Deny or terminate if the provider is non-compliant with any requirement described in subpart B or E of Part 455.

- *Felony convictions*: Deny or terminate if the provider, any person or organization with an ownership or control interest in the provider, or any managing employee or managing organization of the provider was, within the preceding 10 years, convicted of a Federal or State felony offense that the State determines is detrimental to the best interests of its Medicaid program or CHIP and its beneficiaries.

- *Prescribing Authority:* Deny or terminate if: (1) a physician's or practitioner's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked or is surrendered in response to an order to show cause.

- *Misuse of enrollment:* Terminate if the provider knowingly sells to or allows another individual or entity to use its enrollment to bill Medicaid or CHIP.

- *Improper prescribing practices:* Terminate the physician or practitioner has a pattern or practice of prescribing Medicaid or CHIP drugs that is abusive, represents a threat to the health and safety of Medicaid or CHIP beneficiaries, or fails to meet Medicaid or CHIP requirements.

- *Abusive ordering, certifying or referring of Medicaid or CHIP services or item:* The physician or practitioner has a pattern or practice of ordering, certifying or referring Medicaid or CHIP services or items that is abusive, represents a threat to the health and safety of Medicaid or CHIP beneficiaries, or otherwise fails to meet Medicaid or CHIP requirements.

(a) Stakeholders Impacted

The principal impacted parties would be the States and Medicaid and CHIP providers.

(b) Benefits

We believe that our proposed denial and revocation grounds would: (1) facilitate greater consistency between Medicare and Medicaid as well as between State Medicaid agencies and CHIPs; and (2) protect Medicaid and CHIP from non-compliant providers.

(c) Savings, Costs, and Transfers

We are unable to assess the cost impact of these provisions or calculate potential transfers for two main reasons. First, as these are new or expanded grounds, we have no precedent in Medicaid or CHIP upon which we can establish an estimated impact. Second, although most of these bases are duplicated in § 424.535(a) with respect to Medicare, we do not believe that using the annual number of Medicare revocations on these grounds as a basis for calculating the likely number of Medicaid and CHIP terminations is appropriate. This is because the number of situations in which these Medicaid and CHIP termination situations will arise may be very different from that for Medicare. This is particularly true because these grounds are discretionary in Medicare but would be mandatory in Medicaid and CHIP (absent a State finding that the termination would not be in the best of the Medicare program or CHIP). States may therefore have considerably more terminations than Medicare. Too, some States, for instance, may already have several of these denials and termination reasons (or variations of them) under State law, meaning there would be no material increase or decrease in denials or terminations for such provider activity.

Due to this uncertainty, we request comments from interested parties (in particular, the States) on the potential impact of these proposed bases. We are particularly interested in comments regarding whether the States currently use termination reasons similar to those we are proposing and, if so, how frequently.

As with our proposed Medicare revocation reasons, we believe there could be savings or transfers from terminations of Medicaid or CHIP enrollment, though we are unable to estimate a potential amount.

(2) Medicaid and CHIP Application Fee (§ 455.460)

Consistent with § 455.460, States must collect the applicable provider enrollment application fee from a prospective or revalidating provider. There are exceptions, though. These include, but are not limited to, providers identified in § 455.460(a)(2) that--

- Are enrolled in either Medicare or another State's Medicaid program or CHIP.

- Have paid the applicable application fee to a Medicare contractor or another State.

In general, application fees are intended to cover the State's cost of screening the provider and the application. States screen a provider's application at the same level (limited, moderate, or high) that CMS uses for that same provider type under § 424.518. However, States under § 455.452 may screen an application at a higher level (using more stringent methods) than that required by part 424, subpart E.

Some States have expressed reluctance to screen at higher levels under § 455.452 because of the inability to collect an application fee under § 455.460 to cover the additional costs. States therefore have occasionally been unable for financial reasons to use enhanced screening methods when the State believed they were necessary. We are concerned that this has resulted in certain Medicaid providers having been insufficiently screened. To remedy this, we are proposing that § 455.460(a)(2)(A)(*1*) and (*2*) would not apply if the State is screening the provider at a higher level under subpart E than the Medicare contractor or other State to which the provider paid the fee; in this situation, the State would be permitted to collect an application fee from the provider consistent with § 455.460.

(a) Stakeholders Impacted

The States and Medicaid/CHIP providers would be principally affected.

(b) Benefits

We believe our proposal could make States more willing to engage in enhanced screening when they believe it is warranted. This, in turn, could lead to greater scrutiny of potentially problematic providers.

(c) Savings, Costs, and Transfers

As this would be a new provision, we have no historical data to help us ascertain its impact. We thus request comments from interested parties, especially States, regarding the frequency with which States might request a fee under our proposal, the expected number of impacted providers with that State, and what the fee amount might be. We believe this would

help us assess the cost of our proposal in terms of the total fee payments (which would qualify as a transfer from providers to the States).

We are unable to assess the dollar amount that might be saved from providers that were terminated due to this stricter screening, though we do anticipate some savings.

(d) General Solicitation of Comments from States Regarding Our Enrollment Provisions

For all of our proposed Medicaid and CHIP provider enrollment provisions, we also ask States to identify any impact they may experience in implementing and executing our proposed provisions, including potential costs.

(e) MA Enrollment

We are proposing to require providers that bill MA to be enrolled in Medicare in an approved status in order to receive payment for furnished MA services and items.

(i) Stakeholders Impacted

MA organizations, and providers that bill MA would be the main parties affected.

(ii) Benefits

As explained in much greater detail in section V. of this proposed rule, we believe that the principal benefit of our MA enrollment proposal would be the strengthening of the ability to ensure that providers are adequately screened for program integrity issues before billing MA.

(iii) Savings, Costs, and Transfers

As explained in the ICR section of this proposed rule, we estimate an average annual ICR cost over the first 3 years of this requirement of $11,080,585.

We request comments from stakeholders as to additional costs this requirement might involve, especially the costs to MA organizations of implementation.

We expect that savings would accrue from this greater scrutiny, since providers that do not meet enrollment requirements would be unable to bill MA. Since this is a new requirement, however, we are unable to calculate a savings estimate, though we welcome comments from stakeholders on this topic.

4. Marketplace Program Integrity

a. Stakeholders Impacted

The Marketplace provisions would impact insurance agents, insurance brokers, and insurance web-brokers. Some entities within these categories may qualify as small businesses.

b. Expand Authority to Terminate Agents, Brokers, and Web-brokers' Exchange Participation

We propose to revise 45 CFR 155.220(g)(3) to add participation standards that would prevent agents, brokers, and web brokers that pose unacceptable risk from participating in the FFEs and SBE-FPs. Specifically, agents, brokers, and web-brokers that pose unacceptable risk would not be permitted to register, complete training, or enter into Exchange agreement(s) with CMS.

Additionally, this proposed rule would update § 155.220(g)(3) to allow CMS to immediately terminate agents, brokers, and web-brokers who pose unacceptable risk from participating in the FFEs and SBE-FPs, without waiting 30 calendar days from the date of notice. This proposed rule would also add a definition of "convicted" to § 155.20 in alignment with the Medicare program.

We do not expect the proposed changes to § 155.20 or § 155.220(g)(3) to have a financial impact on agents, brokers, or web-brokers because the changes do not impose any new requirements on them. We also expect these changes to only have minimal impact on CMS' oversight responsibilities because CMS already has systematic access to the data required for implementation. We anticipate that these changes would have benefits, including reducing the amount of taxpayer dollars being inappropriately disbursed, increasing transparency around program integrity oversight of the FFE, and improving public trust with the FFE and the agent, broker, and web-broker community.

We believe disruptions in the broker market will be limited to brokers that pose an undue risk of fraud in FFEs and SBE-FPs. That is, any disruptions in the broker market will be related to fraudulent brokers or dollars that should not have been paid out in the first place. We will

analyze feedback submitted in response to the agent-broker moratoria announcement. In addition, we will analyze the comments received from stakeholders to enrich the newly proposed provision when this rule is finalized.

c. Strengthen CMS' Authority to Terminate and Agent, Broker, or Web-broker for Cause

(1) Opportunity to Refute Determinations of Noncompliance (45 CFR 155.220(g)(3)(i)) and Factors CMS May Consider in Enforcement Determinations (45 CFR 155.220(g)(1)(i))

We propose to revise § 155.220(g)(3)(i) to provide agents, brokers, and web-brokers with an opportunity to refute determinations of noncompliance, with the exception of determinations make under § 155.220(g)(3)(ii) and proposed §§ 155.220(g)(3)(iii)-(iv), prior to the termination of their Exchange Agreement(s) for cause and imposition of other penalties under § 155.220(k)(1), which would replace the existing opportunity to "resolve" identified noncompliance. We also propose to revise § 155.220(g)(1) and add a new paragraph at § 155.220(g)(1)(i) to clarify how CMS would determine whether to terminate an agent, broker, or web-broker's Exchange Agreement(s) and impose a penalty under § 155.220(k)(1) when CMS has made a determination of noncompliance under § 155.220(g)(1).

These proposals are expected to result in minimal compliance costs for agents, brokers, and web-brokers associated with responding to noncompliance determinations. We anticipate this burden would be roughly equivalent to burden associated with providing CMS with information to "resolve" identified noncompliance as operationalized under the current regulations. Similarly, we expect any administrative costs for HHS to implement this change to be done at minimal additional costs and burden. These proposals continue to support the existing benefits of the existing policies that are clarified by these proposed revisions, transparency, accuracy, and efficiency in CMS noncompliance determinations and resulting enforcement actions against agents, brokers, and web-brokers.

(2) Policies to Address Abusive Conduct

We propose to revise 45 CFR 155.220(g)(5) to move from a fraud-based standard to an

abusive conduct-based framework. Additionally, we propose to adjust the standard of proof for suspensions and terminations for cause of an agent, broker, or web-broker's Exchange Agreement(s) by CMS under §155.220(g)(5). We propose to amend § 155.220(j)(2)(i) and § 155.220(j)(2)(ii) by adding illustrative, but not exhaustive examples of behavior that CMS considers abusive conduct and amend § 155.220(j)(4) to exclude these provisions from the good faith exception.

We do not anticipate the proposed changes to § 155.220(g)(5) and § 155.220(j)(2) will result in costs for agents, brokers, and web-brokers because the changes are focused on updating and clarifying internal processes. We anticipate that these changes would support the goals of the existing policies that are clarified by these proposed revisions, including reducing the amount of taxpayer dollars being inappropriately disbursed, increasing transparency around program integrity oversight of the FFE, and improving public trust with the FFE and the agent, broker, and web-broker community.

(3) Extension of the Rebuttal Period

In circumstances where we suspend an agent, broker, or web-broker's Exchange agreement(s) under proposed § 155.220(g)(5), the agent, broker, or web-broker may submit evidence in a form and manner specified by CMS to rebut the allegation(s) within 30 days of the suspension. We propose in revised § 155.220(g)(5)(ii)(B) that if the agent, broker, or web-broker submits such evidence within 30 days of the suspension, CMS will review the evidence and make a determination on whether to lift the suspension within 90 calendar days of the suspension.

We do not anticipate the proposed changes will result in costs for agents, brokers, and web-brokers because these changes do not impose any additional operational requirements or compliance burdens. We anticipate that these changes would have benefits for agents, brokers, and web-brokers seeking to gather information required to demonstrate their compliance during an administrative adjudication. Similarly, we expect this will have benefits to the overall

program integrity of the FFE by allowing greater time for the development of the administrative record.

d. Restriction on Access to the FFEs and Exchange Data from Outside the United States (45 CFR 155.220(j)(2)(ix))

We propose to add 45 CFR § 155.220(j)(2)(ix) to codify existing requirements in the agreements described in § 155.220(d) requiring agents, brokers, and web-brokers to implement and maintain reasonable safeguards to ensure that access and attempted access to the FFEs and SBE-FPs, systems that support the FFEs and SBE-FPs, and personally identifiable information obtained through the FFEs and SBE-FPs occurs only from locations within the United States.

We do not anticipate that agents, brokers, and web-brokers will incur costs associated with maintaining compliance with the codified standard as agents, brokers, and web-brokers are already prohibited from accessing such systems and information from outside the United States as a term of the Exchange Agreement(s) they enter into with CMS.

(1) Regulatory Review Costs for Agents, Brokers, and Web-brokers

We do anticipate there may be regulatory review and training costs for agents, brokers, and web-brokers participating in the Exchanges. In calculating these cost, we assumed approximately 8,046 medical and health service managers (Code 11-9111) would review this proposed rule. This assumption was informed by the 2027 HHS Notice of Benefit and Payment Parameters (NBPP) Final Rule, which uses the same estimate of reviewers when estimating regulatory review costs.[227] The NBPP is CMS' primary annual regulation governing the agency's marketplace programs and is therefore sufficient precedent and an adequate proxy for estimating the number of reviewers. Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimated that the cost of reviewing the proposed rule is $135.54 per hour, including overhead and fringe benefits

[227] https://www.federalregister.gov/documents/2026/05/20/2026-10050/patient-protection-and-affordable-care-act-hhs-notice-of-benefit-and-payment-parameters-for-2027-and

(https://data.bls.gov/oes/#/area/0000000/2025). It would take 5.05 hours for one person to review half of the rule, clarify uncertainties, and disseminate the information to all the relevant decision makers within the organizations, assuming an average word read per minute of 250. Thus, we anticipate that the regulatory review cost for the agent, broker, and web-broker community will be approximately $5,507,301.94. We seek comments on these estimates and assumptions.

5. Clarifying Existing Requirement and Adding a New Unsolicited Beneficiary Contact Prohibition

a. Stakeholders Impacted

The proposed unsolicited beneficiary contact provisions would affect Medicare-enrolled DMEPOS suppliers, Medicare beneficiaries, and CMS. DMEPOS suppliers would be responsible for complying with the applicable beneficiary contact requirements. The provisions are intended to protect Medicare beneficiaries from prohibited unsolicited contact, with CMS responsible for oversight and enforcement of the supplier standards.

b. Regulatory Review Costs for Reading, Clarifying, and Disseminating the Rule, and the Costs of Clarifying the Existing Requirement and Adding a New Unsolicited Beneficiary Contact Prohibition (42 CFR 424.57(c)(11); 42 CFR 424.57(c)(31))

The provision contained in this proposed rule will impact DMEPOS suppliers. In 2025 there were 79,360 approved DMEPOS supplier Medicare enrollments. Using the mean hourly wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing the proposed rule is $67.77 per hour ($135.54 including overhead and fringe benefits).[228] Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 12.688 minutes for the staff to review this provision of the proposed rule (review includes clarification and dissemination). For each entity that reviews this provision of the proposed rule, the estimated cost is $28.66 (12.688 minutes ×

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228 https://data.bls.gov/oesprofile/?year=2025&major_group=110000&occupation=119111&measure=01&areas=INDUSTRY,STATE,MSA

$135.54 per hour). We are estimating that only half of the approved DMEPOS suppliers Medicare enrollments will review this provision of the proposed rule. Therefore, we estimate that the total cost of reviewing this provision of the proposed rule is $1,137,229 ($28.66 × 39,680 reviewers) (where 79,360 approved DMEPOS supplier Medicare enrollments divided by 2 equals 39,680 reviewers). We do not believe that DMEPOS suppliers will incur additional costs beyond the one-time regulatory review cost to review, clarify, and disseminate the proposed rule. The provisions contained in this proposed rule are primarily procedural and do not require DMEPOS suppliers to incur additional operating costs, as DMEPOS suppliers typically maintain such policies and records regarding contact with beneficiaries and furnishing of DMEPOS items to beneficiaries as a usual and customary business practice. We solicit comments on our proposed burden estimates and assumptions.

D. Regulatory Review Costs

Although we request comments from stakeholders on the potential number of reviewers of the Medicare, Medicaid, CHIP, and MA provider enrollment portions of this proposed rule, we will tentatively project – solely for purposes of soliciting comment and only for purposes of this particular proposed rule – we will estimate that 8,250 persons will read these enrollment provisions. Using the May 2025 wage information from the BLS for medical and health services managers (code 11–9111), we estimate that the cost of reviewing this rule is $135.54 per hour, including fringe benefits and overhead costs (https://data.bls.gov/oes/#/area/0000000/2025). Assuming an average reading speed for technical materials of 250 words per minute, we project that it will take approximately 1.5 hours for each person to review these sections. For each person that reviews the rule, the estimated cost is $203.31 (1.5 hours * $135.54). Therefore, we estimate that the total cost of reviewing the provider enrollment sections of this proposed rule is $1,677,308 ($203.31 * 8,250 reviewers).

E. State Medicaid Agency Regulatory Review and Training Costs

We anticipated one medical and health service manager (Code 11–9111) from each of the

50 States, the District of Columbia, and the applicable territories to read, clarify, and disseminate this proposed rule. Including all States and territories (hereafter collectively "States"), there are 56 Medicaid programs in the United States.

It is possible that some of these reviewers will choose not to comment on the proposed rule. Therefore, we assumed that approximately 56 Medicaid programs may review the proposed rule. For these reasons, we think that the number of Medicaid programs in the United States would be a fair estimate of the number of reviewers who are directly impacted by the proposed rule. We are requesting comments on this assumption.

We also recognize that different Medicaid health service managers are in many cases affected by mutually exclusive sections of the proposed rule. However, for the purposes of our estimate, we assume that each Medicaid Health Service Manager reads 50 percent of the proposed rule.

Using the May 2025 mean (average) wage information from the BLS for medical and health services managers (Code 11-9111), we estimated that the cost of reviewing the proposed rule is $135.54 per hour, including fringe benefits and other indirect costs (https://data.bls.gov/oes/#/area/0000000/2025). Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 303.03 minutes (5.05 hours) for the staff to read the proposed rule, which is approximately 75,759 words. For each medical and health services manager (Code 11–9111) that reviews the proposed rule, the estimated cost is (5.05 x $135.54) or $684.48. In part, we estimate that the cost of reviewing this proposed rule by medical and health service managers is $38,330.72 ($684.48 x 56 reviewers).

We also assume that it would take approximately two hours for State Medicaid agencies, medical and health service managers to train their staff on the provisions in this rule. Therefore, the total cost for training is $15,180.48 (2 hours x 56 States x $135.54).

The regulatory review and training costs that would be incurred by States do involve direct transfer of funds because of the 50-percent Federal administrative match.

We acknowledge that these assumptions may understate or overstate the costs of reviewing the proposed rule.

F. Summary of Cost and Benefits from the CRUSH Rule

Table C-B8 is a comprehensive summary of the costs and benefits/savings related to the CRUSH rule over a 10-year period, broken out by provision.

TABLE C-B8: TOTAL COST/COST SAVINGS OF PROPOSED POLICIES BY YEAR (in Millions)

Category of Provisions	Year(s)										
TRANSFERS	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**	**2034**	**2035**	**2036**	**10-year Total**
MA RADV	(2,201.80)	(16,804.20)	(16,813.60)	(13,586.70)	(6,793.30)	(6,793.30)	(6,793.30)	(6,793.30)	(6,793.30)	(6,793.30)	(90,166.10)
Medicaid PERM CAPs	(0.03)	(0.03)	(0.03)	(0.03)	(0.03)	(0.03)	(0.03)	(0.03)	(0.03)	(0.03)	(0.30)
Medicaid NPI Requirements for States	0.36	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0.36
Medicaid/CHIP Beneficiary Eligibility Audits	0.24	0.24	0.24	0.24	0.24	0.24	0.24	0.24	0.24	0.24	2.35
Medicaid/CHIP Managed Care Oversight Policies	0.74	0.74	0.74	0.74	0.74	0.74	0.74	0.74	0.74	0.74	7.40
Medicaid Payment Suspensions Updates	0.05	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.20
Medicaid State Reporting Requirements	0.44	0.44	0.44	0.44	0.44	0.44	0.44	0.44	0.44	0.44	4.40
Medicaid MEQC Deregulation	N/A	N/A	N/A	(11.01)	(11.01)	(11.01)	(11.01)	(11.01)	(11.01)	(11.01)	(77.07)
TOTAL TRANSFER COSTS	**(2,200.00)**	**(16,802.80)**	**(16,812.20)**	**(13,596.31)**	**(6,802.91)**	**(6,802.91)**	**(6,802.91)**	**(6,802.91)**	**(6,802.91)**	**(6,802.91)**	**(90,228.76)**
COSTS	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**	**2034**	**2035**	**2036**	**10-year Total**
ICR Costs to States											
Medicaid PERM CAPs (42 CFR 431.992(a))	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.20
Medicaid PERM CAPs (42 CFR 431.992(e))	0.00395	0.00395	0.00395	0.00395	0.00395	0.00395	0.00395	0.00395	0.00395	0.00395	0.04
Medicaid NPI Requirements for States	0.33	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.33
Medicaid/CHIP Beneficiary Eligibility Audits	0.24	0.24	0.24	0.24	0.24	0.24	0.24	0.24	0.24	0.24	2.35
Medicaid State Reporting Requirements	0.44	0.44	0.44	0.44	0.44	0.44	0.44	0.44	0.44	0.44	4.40
Medicaid MEQC Deregulation	0.00	0.00	0.00	-11.01	-11.01	-11.01	-11.01	-11.01	-11.01	-11.01	-77.07
TOTAL ICR COSTS TO STATES	**1.03**	**0.70**	**0.70**	**-10.31**	**-10.31**	**-10.31**	**-10.31**	**-10.31**	**-10.31**	**-10.31**	**-69.75**
Other Costs to States	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**	**2034**	**2035**	**2036**	**10-year Total**
Medicaid/CHIP Managed Care Oversight Policies	0.74	0.74	0.74	0.74	0.74	0.74	0.74	0.74	0.74	0.74	7.40
Medicaid Payment Suspensions Updates	0.05	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.02	0.20
Other Costs to States	**0.79**	**0.76**	**0.76**	**0.76**	**0.76**	**0.76**	**0.76**	**0.76**	**0.76**	**0.76**	**7.60**
TOTAL COSTS TO STATES	**1.82**	**1.46**	**1.46**	**(9.55)**	**(9.55)**	**(9.55)**	**(9.55)**	**(9.55)**	**(9.55)**	**(9.55)**	**(62.11)**
Private Costs	**2027**	**2028**	**2029**	**2030**	**2031**	**2032**	**2033**	**2034**	**2035**	**2036**	**10-year Total**
Medicaid NPI Requirements for Providers (PCAs/HHAs)	14.81	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	14.81
MA RADV ICR	60.20	22.57	22.57	22.57	22.57	22.57	22.57	22.57	22.57	22.57	263.33
MA & Part D Mandatory Reporting ICR	1.09	1.09	1.09	1.09	1.09	1.09	1.09	1.09	1.09	1.09	10.90
MA & Part D RADV & Mandatory Reporting Regulatory Review Costs	0.20	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.20
Provider Enrollment ICR	12.22	12.22	12.22	12.22	12.22	12.22	12.22	12.22	12.22	12.22	122.20
DMEPOS Supplier Survey Requirements	2.09	2.09	2.09	2.09	2.09	2.09	2.09	2.09	2.09	2.09	20.90
Provider Enrollment Regulatory Review Costs	1.68	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.68
Marketplace Regulatory Review Costs	5.51	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	5.51
Clarifying Existing Requirement and Adding a New Unsolicited Beneficiary Contact Prohibition Regulatory Review Costs	1.14	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	1.14
TOTAL PRIVATE COSTS	**98.94**	**37.97**	**37.97**	**37.97**	**37.97**	**37.97**	**37.97**	**37.97**	**37.97**	**37.97**	**440.67**
TOTAL COSTS	**100.76**	**39.42**	**39.42**	**28.41**	**28.41**	**28.41**	**28.41**	**28.41**	**28.41**	**28.41**	**378.51**

G. Alternatives Considered

1. Medicaid and CHIP Program Integrity

a. PERM CAPs (§§ 431.992(a), (b)(3)(ii)(E), (b)(3)(ii)(F), (c), and (e) and 431.1010(b)(2)(ii))

We considered maintaining the current requirements in § 431.992. Under this alternative, each of the 17 States in an annual PERM cycle would continue to submit separate Medicaid and CHIP CAPs, and affected States would continue to submit eligibility corrective action implementation updates every other month. This alternative would avoid regulatory changes, but it would preserve duplicative submissions, require 85 additional responses and 714 additional burden hours each year compared with the proposed approach, and leave the current CMS review and revision process unstated in the regulation. We determined that requiring one combined CAP, reducing the update frequency to every 6 months, and formalizing the review and revision process would reduce administrative burden while preserving program-specific requirements and CMS oversight.

b. Medicaid Managed Care Capitation Payments and Reporting of Enrollee Changes in Circumstances (§§ 438.3(c)(2), 438.608(a)(3), and 438.608(d)(1)(iv))

We considered maintaining the current requirements. Managed care plans would continue to notify States promptly when they receive information about an enrollee's death or change of residence, without a specified 30-calendar-day deadline, and States would continue to administer capitation payments and recoveries under existing requirements. This alternative would avoid implementation costs attributable to the proposed changes, but it would leave States and managed care plans without the proposed reporting deadline and recovery clarifications. The burden analysis estimates $1.67 million in one-time setup costs and, for an illustrative 100,000 reports, $1.88 million in annual processing costs under the proposed approach. These amounts should not be treated as the savings from maintaining current requirements because managed care plans and States already perform some reporting and processing, and the number of additional reports is unknown. We determined that a defined reporting deadline and clearer

recovery procedures would help States address changes in enrollee circumstances and improper capitation payments more consistently. We cannot quantify the additional recoveries attributable to the proposal.

c. Revisions to 455.17 Reporting Requirements

CMS does not currently collect this information from states. The alternative to updating and adding the updated requirements is to continue not collecting the information or to collect the information without the enhanced reporting requirements.

d. Medicaid Payment Suspensions Updates (§ 455.23)

- *No Action (Status Quo).* Under the status quo, the inconsistencies, gaps, and inefficiencies identified above would persist. States would continue to apply divergent standards for CAF determinations, payment suspensions would continue to lapse due to law enforcement declinations, good cause exceptions would continue to be overutilized, and CMS would continue to receive only annual reporting data. This alternative was rejected because it fails to address the documented program integrity vulnerabilities and does not reflect 15 years of implementation experience.

- *Mandatory (Rather Than Permissive) Reliance on External CAF Determinations.* CMS considered but did not propose requiring SMAs to accept all externally determined CAFs without any independent review. This alternative was rejected because it would eliminate State flexibility and could result in payment suspensions being initiated based on CAF determinations that may not be fully applicable to the Medicaid context. Moreover, it would not comply with current statutory language referencing CAF determinations by the State. The proposed permissive standard appropriately preserves State discretion while reducing unnecessary duplication.

- *Mandatory Payment Suspension Maintenance.* CMS considered but did not propose requiring SMAs to maintain payment suspensions in all cases where a CAF remains unresolved, regardless of law enforcement declination. This alternative was rejected because it would

eliminate State flexibility and could result in open-ended suspensions in cases where the underlying investigation has effectively concluded. Moreover, it would not comply with current statutory language requiring a pending investigation. The proposed permissive standard with quarterly redetermination requirements appropriately balances these considerations.

- *Monthly Reporting.* CMS considered but did not propose increasing the reporting cadence to monthly rather than quarterly. This alternative was rejected because the incremental oversight benefit of monthly reporting was not considered sufficient to justify the additional administrative burden on SMAs, particularly given that the primary data sources (case tracking systems) may not be updated this frequently.

e. National Provider Identifier (NPI) Requirements for Medicaid Providers (§ 455.440)

We considered an alternative in which we would encourage, but not require, States to maintain another unique identifier for providers who are not eligible to obtain an NPI. While we encourage this as a best practice, we are not currently proposing it as a requirement, but we may adopt it, or other approaches in the final rule based on comments and evidence received.

Instead, we are focusing potentially mandating NPIs, which are a national standard and covers the vast majority of providers in the majority of states, and we believe the most effective approach to achieving our program integrity goals without imposing unnecessary burden for non-traditional or atypical provider types. We believe the current proposal strikes the right balance by establishing a consistent enterprise-wide identifier where it is most impactful. However, we invite comments on alternative approaches for reliable provider identification, in particular for providers where direct oversight is limited and fraud risk is elevated, for example those providers furnishing services in home- and community-based settings. Please submit supporting data and explain how each approach would address the issues at hand. Depending on the comments and evidence received, the final rule may adopt the proposed approach, the alternative described here, or a variation within the range described in this notice.

f. Requirements for Program Integrity Corrective Action Plans (§ 455.600, *et seq.*)

We considered maintaining the status quo, relying on our existing, limited authorities to encourage State compliance. However, we determined that this alternative would allow repeat audit findings and program vulnerabilities to persist without a formalized enforcement mechanism, undermining the overarching goals of Medicaid program integrity modernization.

g. Medicaid Beneficiary Eligibility Audits (§ 455.700, *et seq*.)

We considered, but did not propose, a targeted methodology for the Medicaid and CHIP beneficiary eligibility audits. Targeted beneficiary eligibility audits would only focus on a subset of Medicaid and CHIP beneficiaries, such as only those from a specific eligibility category. It was determined that a targeted audit methodology would not be compliant with section 1903(u) of the Act and therefore, could not lead to potential eligibility-related disallowances. We also considered, but ultimately did not propose, selecting States for eligibility audits exclusively using a risk-based analysis. To ensure more equitable treatment, we propose auditing every State on a minimum 5-year audit cadence, while also selecting a few additional States each year based on their risk score.

h. Enhanced Electronic Visit Verification (EVV) Requirements

We considered, but ultimately did not propose, requiring States to implement claims processing edits for services subject to Federal or State EVV requirements, which would mean that applicable claims without a matching EVV record would be rejected automatically. This regulatory requirement would likely require significant investments from States and the Federal Government to upgrade Medicaid systems. We did not propose this alternative because of unresolved operational issues associated with implementing automatic claims edits, including potential variations in State EVV and claims processing systems.

2. Medicare Advantage and Medicare Part D Program Integrity

a. Risk Adjustment Data Validation (RADV)

This rule includes transfers from MA organizations to the Federal Government. The aggregate impact of each of these over 10 years is approximately $90.2 billion (see Table C-B8).

Various alternatives to this rulemaking were considered, including the use and timing of extrapolation. These alternatives are described in this section of this rule.

b. Alternatives Related to the Extrapolation of RADV Findings

As an alternative to our decision to extrapolate our RADV audits beginning in PY 2018, we considered policies whereby we would not extrapolate and would only collect improper payments associated with sampled enrollees as a result of RADV audits. While such a policy would likely be favorably received by MA organizations, it would result in a drastic reduction in potential recoveries and dilute the sentinel impact that the RADV program has on reducing the Part C improper payment rate. More specifically, we estimate that total non-extrapolated overpayment recoveries would be approximately $89.7 billion less than total extrapolated overpayment recoveries for the time period of 2027-2036. Further, the RADV audit program would have a negative return on investment of approximately $3.2 million per calendar year. This assumes the annualized monetized cost of the contract-level RADV audit program is approximately $48 million and annualized monetized non-extrapolated recoveries of $44.8 million. CMS has a fiduciary responsibility to reduce and recover improper payments for the Medicare Trust Funds. Not extrapolating and incurring a negative return on investment for the audit program would be in direct conflict with our responsibilities under the PIIA to reduce improper payments and fiduciary responsibility to recover improper payment from the Medicare Trust Funds, and therefore, this alternative was not an acceptable alternative to CMS.

c. Alternatives Related to the Application of an FFS Adjuster to RADV Improper Payment Determinations

As an alternative to our proposal to not apply an FFS Adjuster to our RADV overpayment determinations, we considered a policy whereby we would apply an FFS Adjuster to RADV overpayment determinations. We believe such an approach through regulatory or other means would be an unsupportable and unreasonable interpretation of the Act.

As previously described, we have determined that the “actuarial equivalence” and “same

methodology" provisions do not apply to the obligation of an MA organization to report and return overpayments that they have identified, including overpayments due to lack of medical record support for diagnoses, or their obligation to return overpayments identified based on a RADV audit. In *UnitedHealthcare*, the D.C. Circuit held that actuarial equivalence and same methodology do not apply to the MA organizations' obligation to report and return overpayments that they have identified, including overpayments arising from the MA organizations' submission of and payments based on diagnoses unsupported by their beneficiaries' medical records. Although *UnitedHealthcare* addressed the enforceability of the Part C overpayment regulation, its reasoning applies just as strongly in the RADV context and supports our proposed conclusion that the use of an FFS Adjuster is neither required nor appropriate for a RADV audit.

We also believe that it would be unreasonable to interpret the Act as requiring a minimum reduction in payments in one provision (the coding pattern provision), while at the same time prohibiting CMS in an adjacent provision (the actuarial equivalence provision) from enforcing those longstanding documentation requirements (by requiring an offset to the recovery amount calculated for CMS audits). To the contrary, because the Act requires CMS to reduce payments to MA organizations by at least a specific minimum percentage, the only reasonable interpretation of the Act is that CMS would pay MA organizations at those reduced rates, under the existing payment model,[229] and enforce the longstanding documentation requirements through CMS' audits.

d. Alternatives Related to Mandatory Reporting of Fraud, Waste, and Abuse

An alternative to this proposal would be to keep the existing policy requirements at §§ 422.503(b)(4)(vi)(G)(4) through (7) and 423.504(b)(4)(vi)(G)(4) through (7), that state MA organizations and Part D plan sponsors are required, in accordance with §§

[229] Any changes to the CMS-HCC risk adjustment model are published in the annual Rate Announcement.

422.503(b)(4)(vi)(G)(5) and 423.504(b)(4)(vi)(G)(5), to report information concerning: (1) any payment suspensions implemented by a plan sponsor, pending the investigation of credible allegations of fraud by a pharmacy, which must be implemented in the same manner as the Secretary's implementation under section 1862(o)(1) of the Act; and (2) investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the plan sponsor related to the inappropriate prescribing of opioids to the Health Plan Management System (HPMS) Fraud, Waste, and Abuse (FWA) Reporting Module. While CMS currently encourages plan sponsors to report referrals of substantiated or suspicious fraud, waste, or abuse to CMS, it is not mandatory. However, as described in section IV. of this proposed rule, CMS believes that requiring the reporting of referrals of substantiated or suspicious FWA mandatory for MA organizations and Part D plan sponsors, as well as expanding the required reporting of credible allegation of fraud payment suspensions by pharmacies to all provider and supplier types will strengthen oversight of the Medicare Part C and Part D programs, as this information is valuable in assisting with investigations, referrals to law enforcement, and trend monitoring. In addition, more stringent reporting requirements would allow CMS to appropriately share the more robust data on referred providers or suppliers with other MA organizations and Part D contracts on a quarterly basis to assist in their own internal fraud, waste, and abuse efforts. Data transparency and information sharing with our partners are at the core of CMS' strategy to crush fraud.

An alternative for estimating regulatory review cost includes assuming one reader per parent organization. Using parent organizations instead of contracts would reduce the number of reviewers to approximately 300, and this would reduce the total cost of reviewing by 69 percent. However, we believe it is likely that reviewing will be performed at the contract level. The argument for this is that a parent organization might have local reviewers; even if that parent organization has several contracts that might have a reader for each distinct geographic region, to identify effects of provisions specific to that region.

3. Provider Enrollment Program Integrity

There are number of alternatives we considered.

First, we considered reproposing with only slight modifications our proposal in our March 1, 2016, provider enrollment proposed rule (81 FR 10720) to give CMS the authority to reject surety bonds from a surety that failed to make a required payment to CMS. However, we believe that adhering to the general principles of 31 CFR 223 regarding (1) surety bond declination and (2) rebuttal rights for sureties was the better approach, for it would facilitate a more robust process for all parties.

Second, we contemplated indefinitely continuing with the existing preclusion list for MA providers. As we explained in section V. of the proposed rule (81 FR 10720), though, we are very concerned about providers potentially billing MA without the strict screening that the fee-for-service provider enrollment process affords.

Third, and with respect to our Medicaid and CHIP provider enrollment proposals, we considered (1) making our proposed new denial and termination grounds in § 455.416 discretionary and (2) requesting more information from providers under §§ 455.104 and 455.106 (such as additional adverse actions) than we proposed to collect. With the former, we decided to make the grounds mandatory to remain consistent with the mandatory nature of most of § 455.416's existing reasons and to help facilitate consistency between States; discretionary grounds, we believe, would lead to inconsistent determinations across States. Regarding the data collection, we did not go beyond what we proposed in order to limit the burden on providers.

We wish to emphasize that the goal of our enrollment provisions is not to burden providers and suppliers, particularly small businesses. We recognize the concerns that some stakeholders expressed in their comments on the CY 2027 HH PPS proposed rule regarding the enrollment provisions in that proposed rule. We also stress that we will only take denial and revocation action under our proposals only when genuinely warranted after a thorough and careful review of the facts and circumstances of the case; we are well aware of the impact that a

revocation can have on a provider or supplier. Nonetheless, we have an obligation to protect the Medicare, Medicaid, CHIP, and MA programs, their beneficiaries, and the taxpayers (which includes providers and suppliers themselves) from improper payments and fraud, waste, and abuse. This is the overriding reason for our enrollment proposals, all of which we feel are necessary to target significant program vulnerabilities we have seen.

4. Marketplace Program Integrity

Regarding the opportunity to refute determinations of noncompliance, CMS considered retaining the existing "resolved to the satisfaction of HHS" standard in § 155.220(g)(3)(i) without modification but determined providing agents, brokers, and web-brokers with an opportunity to refute determinations of noncompliance or submit information for CMS' consideration before enforcement action is taken improves procedural clarity and fairness as discussed in more detail above in this proposed rule. CMS also considered retaining the existing "sufficiently severe" standard in § 155.220(g)(1) as the sole basis for determining whether to terminate an agreement for cause and impose other penalties after making a finding of noncompliance, with the exception of determinations made in accordance with § 155.220(g)(3)(ii) through (iv) as proposed in this proposed rule. CMS determined that relying solely on that standard may not adequately account for the full range of circumstances relevant to enforcement determinations, including repeated or escalating noncompliance that may collectively result in significant consumer harm or risks to Exchange operations. CMS further considered adopting a more prescriptive framework establishing fixed numerical thresholds or specific categories of violations that would automatically result in termination or other penalties. CMS declined to adopt such an approach because it would reduce flexibility and may not appropriately account for the varying factual circumstances presented in individual cases.

We considered leveraging the existing regulatory standards for abusive conduct cases, which allow enforcement action against an agent, broker, or web-broker engaging in noncompliance under § 155.220(g)(1) through (3). However, the current noncompliance

standards do not allow for an immediate suspension of an agent, broker, or web-broker's Exchange Agreement(s), which is critical for abusive conduct cases that often involve high-risk behavior and imminent consumer harm. We determined that updating § 155.220(g)(5) to an abusive-conduct standard from a fraud-based standard would better reflect the types of cases identified during our investigations, improve transparency on CMS' enforcement action processes, allow CMS to address abusive conduct quickly, and reduce consumer harm.

Finally, CMS considered continuing to address restrictions on foreign access solely through agreement terms entered into under § 155.220(d) rather than codifying these requirements in regulation. HHS determined that codifying these standards in regulation would provide greater clarity, transparency, and enforceability regarding the obligations of agents, brokers, and web-brokers and would ensure that violations are subject to the full range of remedial actions available under § 155.220. CMS also considered adopting more technology-specific requirements, such as mandating particular technical controls or security measures, but declined to do so because technical specifications may become outdated over time and may be more appropriately addressed through operational guidance or Exchange agreement(s) requirements.

5. Clarifying Existing Requirement and Adding a New Unsolicited Beneficiary Contact Prohibition

An alternative to this proposal would be to keep the existing policy prohibiting unsolicited beneficiary contact by DMEPOS suppliers and their agents when supplying a Medicare covered item by telephone. However, as described in section VII. of this proposed rule, DMEPOS fraud, waste, and abuse in the Medicare program remains a serious problem that has placed billions of taxpayer dollars at risk and may result in beneficiary harm. We believe that the proposed clarification and addition will strengthen program integrity safeguards for the Medicare program and reduce fraudulent billing for Medicare DMEPOS.

H. Accounting Statement and Table

As required by OMB Circular A-4, we have prepared an accounting statement in Table C-B9 showing the classification of the impact associated with the provisions of this rule. Monetary annualized benefits and non-budgetary costs are presented using 3 percent and 7 percent discount rates. The annualized costs of $46.08 million reflect the costs accruing to Providers (PCAs/HHAs), MA RADV ICR, MA & Part D Mandatory Reporting ICR MA & Part D RADV & Mandatory Reporting Regulatory Review Costs, and Provider Enrollment ICR. Meanwhile, the saving accruing to states results from the annual burden from 1,326 hours to 612 hours, and these savings to States do not come at the expense of high-risk recipients. However, most of the annualized transfers of $9,335.20 derive from businesses or high-risk recipients back to the federal government. These transfers derive from the GAO recommendations to focus on contracts at higher risk for improper payments, over the next ten-year period from 2027-2036, with the total estimated overpayments (with extrapolation) over the time period of $90.2 billion (see Table C-B8). The impact on these high-risk recipients cannot be determined at this time. Thus, we seek comments from the public to aid in understanding the impact these transfers will have on these high-risk recipients.

TABLE C-B9: ACCOUNTING STATEMENT (MILLIONS $)

Category	Estimate	Year	Source
Annualized monetized costs *:			
7% Discount	46.08	2027-2036	RIA
3% Discount	44.91	2027-2036	RIA
Annualized monetized costs to States:			
7% Discount	(5.39)	2027-2036	RIA
3% Discount	(5.86)	2027-2036	RIA
Annualized monetized transfers:			
7% Discount	(9,335.20)	2027	RIA
3% Discount	(9,165.43)	2027	RIA

I. Initial Regulatory Flexibility Act (IRFA)

The IRFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the IRFA, HHS estimates that many impacted entities are small entities, as that term is used in the IRFA, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business. Small entities include small businesses,

nonprofit organizations, and small governmental jurisdictions. Individuals and states are not included in the definition of a small entity. Executive Order 13272 requires that HHS thoroughly review rules to assess and take account of their potential impact on small businesses, small governmental jurisdictions, and small organizations (as mandated by the IRFA).

If a proposed rule has a significant economic impact on a substantial number of small entities, then the proposed rule must discuss steps taken, including alternatives considered, to minimize the burden on small entities. The IRFA does not define the terms "significant economic impact" or "substantial number". The SBA advises that this absence of statutory specificity allows what is "significant" or "substantial" to vary, depending on the problem that is to be addressed in rulemaking, the rule's requirements, and the preliminary assessment of the rule's impact. Nevertheless, HHS typically considers a "significant" impact to be 3 to 5 percent or more of the affected entities' costs or revenues and a "substantial number" to be greater than 5 percent of entities.

The IRFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the IRFA, we estimate that there are some entities that can be considered small entities as that term is used in the IRFA (including small businesses, nonprofit organizations, and small governmental jurisdictions). The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $9.0 million to $47.0 million in any 1 year) as of 2023). The SBA has recently updated this threshold in 2025, which has resulted in more hospitals and health care providers.[230] Given that there will be more hospitals and health care providers, the costs estimated because of this rule could be distributed more widely, and therefore each entity would end up paying a smaller share.

1. Objectives and Legal Basis

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230 Federal Register :: Small Business Size Standards . .

CMS' current Medicare, Medicaid and CHIP, and marketplace program integrity frameworks contain outdated, inconsistent, or incomplete requirements across several regulatory areas. These gaps limit CMS' ability to detect fraud, hold States accountable, and recover improper payments. The provisions in this rule discuss these gaps by modernizing reporting, clarifying enforcement authority, and closing structural vulnerabilities in oversight tools. Small businesses, including DMEPOS suppliers, insurance agents, brokers, and web-brokers would face minimal costs for implementing the provisions discussed in this rule. At this time, we cannot determine the cost for each impacted industry, but as can be seen in Table C-B13, if we assume the annualized costs of $46.08 million are distributed evenly over each impact entity, then that cost would be a minimal cost of $127.65. We are seeking comments from the public regarding this assumption.

Thus, we are proposing enhancements to our DMEPOS supplier surety bond process under § 424.57(d). This rule includes a proposal to clarify the existing prohibition against unsolicited beneficiary contact by DMEPOS suppliers to make explicit the inclusion of third-party entities acting as the agents of DMEPOS suppliers; and to clarify that the prohibition against unsolicited beneficiary contact by telephone refers to a telephone call or message, including text messages. This rule also includes a proposal to add a new supplier standard under 42 CFR 424.57(c)(31) to prohibit unsolicited beneficiary contact by DMEPOS suppliers and their agents when supplying a Medicare-covered item by direct messages from social media platforms, email messages without opt-out features, and door-to-door in-person solicitation, unless a specified exception applies. At this time, we cannot determine how much revenue is currently being generated by these practices that are being banned.

Fraudulent billing for Medicare DMEPOS continues to be a major concern. Despite an existing prohibition on unsolicited beneficiary contact by telephone, DMEPOS suppliers and third parties acting as their agents are targeting Medicare beneficiaries with unsolicited text messages and other direct messages, door-to-door in person solicitation, unwanted telephone

calls, and other means to engage in high-pressure marketing tactics and deceptive lead generation that allow DMEPOS suppliers to bill Medicare for medically unnecessary or unneeded items, or items that are never supplied at all. These changes are necessary to help ensure that legitimate DMEPOS suppliers are furnishing medically necessary items of DMEPOS to Medicare beneficiaries consistent with Medicare requirements, which we believe would assist in protecting the Trust Funds and Medicare beneficiaries. There could be a large reduction in revenue for these businesses, but at this time we are unable to estimate such reductions.

Additionally, this rule proposes a number of additions and amendments to 45 CFR 155.20 and § 155.220 to improve the integrity of the FFE, reduce abusive conduct by agents, brokers, and web-brokers, and better protect consumers within the FFE. We are proposing to amend § 155.20 to add a definition of "convicted" and "credible allegation of abusive conduct". We are also proposing to add participation standards for agents and brokers to § 155.220(g)(3), which would prevent agents and brokers that pose unacceptable risk from participating in the FFE. Moreover, we are proposing to amend § 155.220(g)(5) to increase transparency around program integrity oversight of the FFE and further strengthen our administrative actions against suspected bad actors and amend § 155.220(j)(2)(i) and (ii) by adding specific examples of behavior that CMS considers abusive conduct. At this time, we are unable to determine how much revenue will be lost to how many businesses because of this provision.

To further strengthen oversight, improve the fairness of enforcement proceedings following findings of agent, broker, and web-broker noncompliance as defined in § 155.220(g)(2), we are proposing additional revisions to § 155.220. Specifically, to increase transparency and to help ensure accuracy and efficiency in CMS noncompliance determinations and resulting enforcement actions, we propose to amend § 155.220(g)(3)(i) to replace the existing opportunity for agents, brokers, and web-brokers to "resolve" noncompliance determinations before CMS terminates their Exchange Agreements(s) and imposes other

penalties with an opportunity to "refute." At this time, we are unable to determine if these penalties will be cost to small entities.

We also propose codifying factors that CMS would consider when determining whether to terminate an agent, broker, or web-broker's Exchange agreement(s) with the FFE for cause and to impose penalties other than termination under 155.220(k)(1) after making a noncompliance determination. In addition, we propose to amend § 155.220(h) to clarify that agents, brokers, or web-brokers may request reconsideration when HHS denies them the right to enter into Exchange Agreement(s) in addition to when HHS terminates their Exchange Agreement(s)." We are seeking comments from the public to aid us in determining how complicated, time-consuming, or costly such requests will be for these small businesses.

We also propose to add a new standard in § 155.220(j) to codify a term in the Exchange Agreement(s), which would prohibit agents, brokers, and web-brokers from accessing and attempting to access FFE and SBE-FPs systems that support the Exchanges, and personally identifiable information obtained through those Exchanges from outside the United States. At this time, we cannot determine the cost for the imposition of this standard nor how time-consuming and costly this will be for these small businesses. We are seeking comments from the public on these issues.

Agents, brokers, and web-brokers may be asked to submit documentation over the course of a noncompliance or abusive conduct investigation and enforcement action.

2. Impacted Entities

Excluding Medicaid and CHIP, MA Organizations, Part D Plan Sponsors, and Part D Plans, discussed in the section IX.C. of this proposed rule (Detailed Economic Analysis), small businesses that would be impacted by this rule include:

- Home Health Agencies and Personal Care Assistants.
- DMEPOS suppliers.
- Physicians.

- Hospices.
- Agents/Brokers, Web-brokers.

Data does not permit us to determine the costs or burdens will be within each industry.

3. Medicaid and CHIP

Title XIX of the Act established the Medicaid program as a federal-state partnership to provide and finance medical assistance to specified groups of eligible low-income individuals and their families. States claim federal matching funds quarterly based on their program expenditures. Medicaid managed care plans and CHIP managed care plans reflect a somewhat consolidated market with a mix of for-profit, non-profit, and government plans. Government plans often mean county run plans, but there are examples of state agencies acting as a plan. Many county plans are PIHP that provide mental health services, with the main exception of HIOs in CA (often called COHS) that provide comprehensive benefits. 2022 survey data suggest that 16 managed care firms (including Aetna, Centene, United Health Care and others) were responsible for approximately 63 percent of the market. The remaining 36 percent of managed care enrollment reflects local/regional managed care companies,[231] which are more likely to be considered small, though data on their size distribution by annual receipt size is limited. This kind of uncertainty makes it very difficult to certify this rule. However, since Medicaid managed care plans and CHIP managed care entities receive 100 percent capitation from the state, we expect that the projected costs associated with the provisions of this proposed rule, if finalized, will be included in their capitation rates. Currently, we cannot quantify the magnitude of these costs that small entities may or may not be able to pass through via capitation rates.

4. Medicare Advantage

Each year, MA organizations estimate costs for the upcoming plan year and then submit bids and proposed PBPs to CMS. These bids project payments to hospitals, providers, and staff

[231] Centers for Medicare & Medicaid Services. (2026). Medicaid Managed Care Enrollment and Program Characteristics 2024. Retrieved from https://www.medicaid.gov/medicaid/managed-care/downloads/2024-medicaid-managed-care-enrollment-report.pdf.

for covered benefits, as well as the cost of plan administration and profits. Because the provisions proposed in this rule would apply to every MA plan and each MA plan must furnish at least the Medicare Part A and Part B benefits, we assume that the cost of implementing the stated provisions would be built into the administrative component of the basic benefit bid. At this point in time, we are unable to quantify these costs. These bids in turn determine one component of the payments of the Medicare Trust Fund to the MA organizations who reimburse providers and subcontractors for their services. A second component of the Trust Fund payment to MA organizations are the rebates, which are a portion of the difference between the basic benefit bid compared to an administratively set benchmark for the MA plan's service area (currently, based on our past and projected experience, rebates vary by plan and are approximately 66 percent). If the bid is below the benchmark, CMS pays an amount equal to the standard bid of the MA organization. However, if the bid is above the benchmark, CMS pays the portion of the cost up to the benchmark and the MA organization bears the extra cost and must charge enrollees a premium for the remaining amount, as set forth in section 1854 of the Act. As the cost of providing services by these entities is covered by a combination of government funding and in some cases by enrollee premiums, MA and Part D plans are not expected to incur burdens or losses because the private companies' costs are being supported by the government and enrolled beneficiaries. This lack of expected burden applies to both large and small MA health plans. Any MA health plans that are considered “small” would be expected to include the costs of compliance with the proposed regulations in their bids, thus avoiding additional burden, since the cost of complying with any regulation is funded by payments from the government and, if applicable, enrollee premiums. Historically, at most two percent of plans bid above the benchmark, and they contain roughly one percent of all plan enrollees. In the present circumstances, we are unable to quantify this burden and costs estimate.

Table C-B10 reports the percentage of MA organizations bidding above the benchmark and the percentage of affected enrollees in recent years. This table reports aggregates of

proprietary bid data collected by the CMS Office of the Actuary (OACT). Unfortunately, this table does not present the direct, compliance burden since data are not available at this time. As shown in Table C-B29, the percentage of plans incurring additional costs by bidding above the benchmark is 0.11 percent in 2024 and 0.07 percent in 2025, while the CMS threshold for what constitutes a significant impact for purposes of the IRFA is 3 to 5 percent. Since at least 99 percent of MA organizations bid below the benchmark in recent years, we estimate that the federal government fully pays these MA organizations their projected costs for providing services to enrollees for the coming year. Unfortunately, we cannot determine at this time if this across-the-board increase in costs would increase the share of bids that bid above the benchmark. The preceding analysis shows that MA plans, whether small or large entities, are not significantly affected by this proposed rule since the vast majority (all but at most 1 percent) will have their costs subsidized by the federal government and would not be materially impacted. Quantifying all such (potentially passed through) costs to small entities is not possible at this time.

TABLE C-B10: PERCENTAGE OF MA ORGANIZATIONS BIDDING ABOVE THE BENCHMARK BY YEAR

Year	Number of Unique Bid IDs that Bid Above the Benchmark	Projected Enrollment in Plans that Bid Above the Benchmark (Member Months)	Number of Unique Bid IDs	Projected Enrollment (Member Months)	Bid ID Percentage	Enrollment Percentage
2024	6	15,635	5,699	328,703,043	0.11%	0.00%
2025	4	99,807	5,600	314,624,972	0.07%	0.03%

a. Direct Health and Medical Insurance Carriers and Government Health Plans (Part D Plan Sponsors)

For the purposes of this IRFA, CMS evaluates Part D Plan Sponsors or health insurance issuers categorized under the North American Industrial Classification (NAICS) code 524114 (Direct Health and Medical Insurance Carriers). Based on the latest available 2022 Statistics of U.S. Business Statistics (SUSB) from the Census Bureau, 803 total firms fall under code 524114.

According to SBA size standards, entities with average annual receipts of $47 million or less would be considered small entities in this category.[232]. CMS examined the premium revenue data from the MLR annual report submissions for the 2023 MLR reporting year and approximately 84 out of 479 issuers of health insurance coverage nationwide have a total premium revenue of $47 million or less.[233] Furthermore, approximately 80 percent of these small issuers belong to non-small holding groups based on the total premium revenue of all associated subsidiaries available in the MLR data. Many, if not all, of these holding group companies are likely to have other non-health lines of business in addition to health plan premium revenue that likely result in their total revenues exceeding $47 million.[234] Therefore, CMS intends to concludes that the Qualified Health Plan or Part D Plan Sponsor on the FFEs population impacted by these proposed policies may unlikely to include small entities and possibly could be excluded from this IRFA. Currently, we are unable to estimate the impact on half of these small Part D Plan Sponsors.

b. Home Health Agencies, DMEPOS Suppliers, Physicians, and Hospices

For the provisions proposed by the Provider Enrollment Program Integrity Policy, Medicare-enrolled providers and suppliers, including hospices (NAICS 623110) durable-medical equipment, prosthetics, orthotics supplies (DMEPOS) suppliers, and physicians (NAICS 6211), and other practitioners who order DMEPOS items or services, would be impacted by the proposed provisions.

According to the SBA's Web site at http://www.sba.gov/content/small-business-size-standards, DMEPOS suppliers may fall into either (NAICS code 456199) All Other Health and Personal Care Retailers, (NAICS code 532283) Home Health Equipment Rental, and (NAICS

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[232] U.S. Small Business Administration. (2024, October 15). Size Standards Tool. Retrieved from https://www.sba.gov/federal-contracting/contracting-guide/size-standards/size-standards-tool.

[233] Centers for Medicare & Medicaid Services. (n.d.). Medical Loss Ratio Data and System Resources. Retrieved from https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.

[234] Based on internal CMS MLR calculations. Source: Centers for Medicare & Medicaid Services. (2025, November 21). Medical Loss Ratio Data and System Resources. Retrieved from https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.

code 423450) Medical, Dental, and Hospital Equipment and Supply Merchant Wholesale. Table C-B11 shows the SBA size standards according to revenue or number of employees, and the total number of DMEPOS businesses identified as small.

TABLE C-B11: DMEPOS SUPPLIERS SIZE STANDARDS (In Millions)

NAICS (6-digit)	Industry Subsector Description	SBA Size Standard/Small Entity Threshold	Total Small Businesses
423450	Medical, Dental, and Hospital Equipment and Supply Merchant Wholesale	Fewer than 200 employees	8,031
532283	Home Health Rental	$41	450
456199	All Other Health and Personal Care Retailers	$9.5	5,421

Source: 2022 Economic Census

Since we are uncertain of the DMEPOS suppliers' composition, we seek comments from the public to aid in understanding the various industries that supply DMEPOS products. So far, we have identified only the three industries in Table C-B30. We note that Non-Employer Statistics (NES) data show an additional 738 nonemployee firms.

c. Agents/Brokers, Web-brokers

We propose to revise 45 CFR 155.220(g)(3) to add participation standards that would prevent agents, brokers, and web-brokers (NAICS 524210) posing undue risk from participating in the FFE and SBE-FPs. Note, NES data only provide data at the 5-digit level but include an additional 128,893 non-employers within the 456190 NAICS code. Nevertheless, we are unable at this time to use the SUSB data to approximate the share of these non-employers that belong to the 456199 NAICS. Agents, brokers, and web-brokers that pose undue risk would not be permitted to register, complete training, or enter into Exchange Agreement(s) with CMS. We are unsure how many are expected to fall under each category. Additionally, this proposed rule would update § 155.220(g)(3) to allow CMS to immediately terminate agents, brokers, and web-brokers who pose undue risk from participating in the FFE and SBE-FPs, without waiting 30 calendar days from the date of notice.

We do not expect the proposed changes to § 155.20 or § 155.220(g)(3) to have a financial

impact on agents, brokers, or web-brokers because the changes do not impose any new requirements on them. Currently, we are unable to determine an estimate of how many agents, brokers, or web-brokers would be impacted. However, we assume that these entities would incur implementation; that is, the costs that would be incurred for their staff to read and implement the provisions proposed in this rule.

We also propose to revise § 155.220(g)(3)(i) to provide agents, brokers, and web-brokers with an opportunity to refute determinations of noncompliance, with the exception of determinations make under § 155.220(g)(3)(ii) and proposed §§ 155.220(g)(3)(iii)-(iv), prior to the termination of their Exchange Agreement(s) for cause and imposition of other penalties under § 155.220(k)(1), which would replace the existing opportunity to "resolve" identified noncompliance. This is explained in detail in the summary of the proposal above. We also propose to revise § 155.220(g)(1) and add a new paragraph at § 155.220(g)(1)(i) to clarify how CMS would determine whether to terminate an agent, broker, or web-broker's Exchange Agreement(s) and impose a penalty under § 155.220(k)(1) when CMS has made a determination of noncompliance under § 155.220(g)(1). The existing standard is that CMS can terminate if an agent or broker's noncompliance is "sufficiently severe." We're clarifying that we'd assess severity based on several enumerated factors. We do not believe that this clarification will impact on the number of terminations.

TABLE C-B12: SBA SIZE STANDARDS FOR APPLICABLE NAICS INDUSTRY CODES*

NAICS Code	Description	SBA Size Standard/Entity Threshold (Millions $)	Total Small Business Count
524114	Direct Health and Medical Insurance Carriers and Government Health Plans	$47	803
621610	Home Health Services	$19	27,140
532283 456199	DMEPOS Home Health Rental	$41	450
	All Other Health and Personal Care Retailers[235]	$9.5	5,421
423450	Medical, Dental, and Hospital Equipment and Supply Merchant	Fewer than 200 employees	8,031
6211	Physicians	$16	141,446
623110	Hospice (Skilled Nursing Facility)	$34	9,709
524210	Insurance Agents/Brokers, Web-brokers	$15	119,114
Total			**312,114**

[235] Data by revenue buckets are not available on Census's SUSB database.

*Note: The SBA has recently proposed (A Proposed Rule by the Small Business Administration on 08/22/2025) to update the size standards of industries, which will (when finalized) include far more hospitals and health care providers: Federal Register :: Small Business Size Standards. https://www.federalregister.gov/documents/2025/08/22/2025-16142/small-business-size-standards-monetary-based-industry-size-standards.

At this time, we are unable to identify what share of the $90 billion in transfers will come from each industry. Nevertheless, based on the SBA size threshold described in Table C-B12, HHS analyzed the revenue for direct health and medical insurance carriers and government health plans, home health services, DMEPOS, physicians, hospice, and insurance agents/brokers, and web-brokers small businesses, which met the SBA criteria for small entities and their anticipated change in revenue, illustrated in Table C-B13. Even though the rule only impacts participants within CMS programs and the count of impacted small firms would be far smaller than the count below would suggest, we do not have that data. That said, the counts below can serve as useful proxies to determine the share of participants within each industry that qualify as small entities. Therefore, to conduct this revenue test, HHS used the total count of firms considered small based on the latest 2022 SUSB data (306,693). Given the lack of granular or disaggregated data at micro-level, it is difficult to determine the impact of only those small firms who are participants in CMS's. Therefore, at this time we assume that the impacts are spread across all the 306,693 firms. Then, HHS calculated the percentage of these small firms that fall into size ranges by receipt ("% of Small Firms" column in Table C-B13). These percentages are applied to the average revenue *for all small entities*, which yields the average revenue for each firm's size. We do not have data for each category. The average revenue for each firm size is then divided by the annualized cost for the identified small businesses (excluding the States costs) of the proposed rule per firm and reflected as a percentage. When the annualized net primary cost estimates were determined, there were $46.08million net annualized costs for the identified industries overall. The net annualized costs for this proposed rule are $46.08 million, meaning each of the 306,963 small businesses incur a net annualized cost of $150.25, regardless of their size by receipts. Currently, we are unable to net out the $90 billion transfer costs from businesses to the federal government. Furthermore, since we do not have the data for only those

small firms who participate in the relevant CMS programs, we used SUSB 306,963 small businesses as an approximate. While the compliance costs would be spread evenly across impact firms in the way we suggest, this is not the case for the $90 billion in transfers from private industry. As was stated, we are unable to determine the impact of these $90 billion transfers at this time.

This resulting percentage ("Revenue Test" column in Table C-B13) is the anticipated revenue test for small firms due to the proposed rule. As a measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 percent and presents this analysis in Table C-B13.

5. Does the Impact on Small Businesses Meet the Two-Part Threshold

As a measure of its significant economic impact on small entities, HHS uses a change in revenue of more than 3 to 5 percent. The agency considers the rule to have a significant impact on a substantial number of small businesses when more than 5 percent of impacted small entities meet the significant economic impact threshold defined above.

According to Table C-A13, the provisions in this proposed rule would have almost no impact (<0.019 percent) on small the small businesses identified.

Moreover, given that the annual revenue for the 5th percentile firm is over $29 billion and 3 percent of this revenue gives a significant impact threshold of a significantly large estimate (> $888 million), then any cost estimates smaller than this estimate will not have a significant impact on a substantial number of small businesses. Assuming the firm size distribution provided in Table C-B13, we expect the annualized costs estimated as a result of this proposed rule to fall below this significant impact threshold. We believe that the threshold for significant economic impact on a substantial number of small businesses will not be reached by the requirements in this proposed rule. At this moment, we are unable to determine the impact of the $90 billion transfers from businesses to the federal government. Even though including the nonemployers

from NES data is important, and shows that very small firms make up a much larger share of the size distribution, we are unable to determine the impact on revenue.

TABLE C-B13: REVENUE TEST FOR THE ECONOMIC IMPACT ON SMALL ENTITIES

Firm Size (by Receipts)	Firm Count	Percent of Small Firms	Average Revenue	Annualized Cost per Firm	Revenue Test
SMALL FIRMS	**306,693**[236]	**100.00%**	**$657,691.93**	$150.25	0.023%
<100,000	40,829	13.31	$32,036.04	$150.25	0.469%
100,000-499,999	123,181	40.16	$157,199.01	$150.25	0.096%
500,000-999,999	59,554	19.42	$320,245.14	$150.25	0.047%
1,000,000-2,499,999	45,024	14.68	$658,073.69	$150.25	0.023%
2,500,000-4,999,999	18,774	6.12	$1,496,155.55	$150.25	0.010%
5,000,000-7,499,999	7,585	2.47	$2,906,440.15	$150.25	0.005%
7,500,000-9,999,999	4,281	1.40	$3,612,879.70	$150.25	0.023%
10,000,000-14,999,999	4,621	1.51	$6,402,942.10	$150.25	0.004%
15,000,000-19,999,999	1,970	0.64	$7,983,371.24	$150.25	0.002%
20,000,000-24,999,999	377	0.12	$20,504,822.28	$150.25	0.001%
25,000,000-29,999,999	211	0.07	$23,949,739.34	$150.25	0.001%
30,000,000-34,999,999	165	0.05	$25,559,327.27	$150.25	0.001%
35,000,000-39,999,999	39	0.01	$33,442,666.67	$150.25	0.000%
40,000,000-49,999,999	82	0.03	$39,102,621.95	$150.25	0.000%
LARGE FIRMS					
Receipts > 49 million	NA	NA	NA	NA	NA

J. Alternatives for Small Entities

As was mentioned previously, this proposed rule would update § 155.220(g)(3) to allow CMS to immediately terminate agents, brokers, and web-brokers who pose undue risk from participating in the FFE and SBE-FPs, without waiting 30 calendar days from the date of notice. As an alternative, CMS would terminate agents, brokers, and web-brokers who pose undue risk from participating in the FFE and SBE-FPs, after 30 calendar days from the date of notice.

Additionally, as was also mentioned previously, we are proposing enhancements to our DMEPOS supplier surety bond process under § 424.57(d). This rule includes a proposal to clarify the existing prohibition against unsolicited beneficiary contact by DMEPOS suppliers to make explicit the inclusion of third-party entities acting as the agents of DMEPOS suppliers; and to clarify that the prohibition against unsolicited beneficiary contact by telephone refers to a telephone call or message, including text messages. This rule also includes a proposal to add a

[236] Data does not include 5,421firms revenue estimates for NAICS 456199 – All Other Health and Personal Care Retail.

new supplier standard under 42 CFR 424.57(c)(31) to prohibit unsolicited beneficiary contact by DMEPOS suppliers and their agents when supplying a Medicare-covered item by direct messages from social media platforms, email messages without opt-out features, and door-to-door in-person solicitation, unless a specified exception applies.

1. Identifying Duplication

CMS confirms that the proposed provisions in this rule do not duplicate efforts of previous rulemaking, but rather, they build upon and refine them to ensure that CMS' current Medicaid and CHIP program integrity framework contains updated, consistent or complete or requirements across several regulatory areas. These requirements will greatly enhance CMS' ability to prevent and detect fraud, hold States accountable, and recover improper payments.

2. Conclusion and Request for Public Comments

CMS concludes that the provisions relevant to impacted entities do not produce a significant economic impact on a substantial number of impacted small businesses. CMS seeks public comments on their assumptions related to the number of direct health and medical insurance carriers and government health plans, home health agencies, personal care assistants, DMEPOS suppliers, physicians, hospices, and agents/brokers, and web-brokers, that could be considered small businesses, small governmental jurisdictions, or small organizations. We request public comments specifically on how the provisions increase or decrease administrative burden for small entities.

For the purposes of the IRFA analysis, CMS concludes that there is not a significant impact on small entities. As a measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 percent. As illustrated by the revenue test in Table C-B13, none of the small firm sizes approached the 3 percent threshold.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the IRFA. For the

purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. Therefore, the Secretary has certified that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals, and as a result we are not preparing an analysis for section 1102(b) of the Act.

K. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2026, that threshold is approximately $193 million. This proposed rule would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $193 million in any 1 year.

L. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications.

M. E.O. 14192, "Unleashing Prosperity Through Deregulation"

Executive Order 14192, entitled "Unleashing Prosperity Through Deregulation" was issued on January 31, 2025, and requires that "any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations."[237] This proposed rule, if finalized as proposed, is expected to be exempt from otherwise-applicable requirements under E.O. 14192, per footnote 1 of the OMB's Accounting Methods.[238]

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238 Accounting Methods under Executive Order 14192. https://www.reginfo.gov/public/pdf/eo14192/Accounting_Methods_under_EO_14192.pdf.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document.

List of Subjects

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, health facilities, health maintenance organizations (HMO), Medicare, penalties, privacy, and reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, emergency medical services, health facilities, health maintenance organizations (HMO), health professionals, Medicare, penalties, privacy, reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 431

Grant programs-health, Health facilities, Medicare, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 438

Citizenship and naturalization, Civil rights, Grant programs-health, Individuals with disabilities, Medicaid, Reporting and recordkeeping requirements, Sex discrimination.

42 CFR Part 447

Accounting, Administrative practice and procedure, Health professions, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 455

Fraud, Grant programs-health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 457

Administrative practice and procedure, Grant programs-health, Health insurance, and Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interests, Consumer protection, Grants administration, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs-health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and youth.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV and the Department of Health and Human Services proposes to ament 45 CFR part 155 as set forth below:

PART 410 – SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

1. Section 410.33 is amended by revising paragraph (g)(2) to read as follows:

§ 410.33 Independent diagnostic testing facility.

* * * * *

(g) * * *

(2) Provides complete and accurate information on its enrollment application. All changes in enrollment information must be reported to the Medicare fee-for-service contractor within 30 calendar days of the change.

* * * * *

PART 417 – HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

2. The authority citation for part 417 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh and 300e, 300e-5, and 300e-9, and 31 U.S.C. 9701.

3. Section 417.478 is amended by—

a. In the introductory text, removing the phrase "to comply with—" and adding in its place the phrase "to comply with all of the following:";

b. In paragraphs (a) and (b), removing ";" and adding in its place ".";

c. In paragraph (c), removing "; and" and adding in its place ".; and

d. Redesignating paragraphs (e)(1) and (2) as paragraphs (e)(1)(i) and (ii).

e. In paragraph (e)(1) introductory text, adding the phrase "Before January 1, 2030." -

f. Revising newly redesignated paragraph (e)(2).

The revisions and additions read as follows:

§ 417.478 Requirements of other laws and regulations.

* * * * *

(e) * * *

(2) Beginning January 1, 2030, —t

(i) The prohibitions, procedures, and requirements of §§ 422.223 and 422.224 of this chapter, which require all providers or suppliers that are types of individuals or entities that can enroll in Medicare in accordance with section 1861 of the Act, to be enrolled in Medicare in an

approved status and prohibit payment to providers and suppliers that are not enrolled in Medicare in an approved status, are excluded by the OIG, are revoked from Medicare under § 424.535, or are on the preclusion list as described in § 423.120(c)(6) and defined in § 423.100, apply to-HMOs and CMPs that contract with CMS under section 1876 of the Act.

(ii) In applying the provisions of §§ 422.223 and 422.224 of this chapter under paragraph (e)(2) of this section, references to part 422 of this chapter must be read as references to this part, and references to MA organizations as references to HMOs and CMPs.

* * * * *

4. Section 417.484 is amended by –

a. Redesignating paragraph (b)(3) as new paragraph (b)(3)(i).

b. In new redesignated paragraph (b)(3)(i), removing the phrase "That payments" and adding in its place the phrase "Before January 1, 2030, that payments" .

c. Adding paragraph (b)(3)(ii).

The addition reads as follows:

§ 417.484 Requirement applicable to related entities.

* * * * *

(b) * * *

(3) * * *

(ii) Beginning January 1, 2030, that payments must not be made to providers and suppliers that are eligible to enroll in Medicare in accordance with section 1861 of the Act but are not enrolled in Medicare in an approved status.

PART 422 – MEDICARE ADVANTAGE PROGRAM

5. The authority citation for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

6. Section 422.2 is amended by revising the introductory text of the definition for "Preclusion list" to read as follows:

§ 422.2 Definitions.

* * * * *

Preclusion list means, before January 1, 2030, and with respect to this part, a CMS compiled list of individuals and entities that—

X. Section 422.204 is amended by revising paragraph (c) to read as follows:

§ 422.204 Provider selection and credentialing.

* * * * *

(c)(1) Before January 1, 2030, an MA organization must follow a documented process that ensures compliance with the preclusion list provisions in § 422.222.

(2) Beginning January 1, 2030, an MA organization must follow a documented process that ensures compliance with the provisions of § 422.223.

7. Section 422.222 is amended by adding the following opening paragraph before paragraph (a): "The provisions of this section apply before January 1, 2030."

8. Adding § 422.223 to read as follows:

§ 422.223 Enrollment for contracted and non-contracted individuals and entities.

(a) *General enrollment requirement.* Beginning January 1, 2030, providers that are types of individuals or entities that are eligible to enroll in Medicare (in accordance with section 1861 of the Act) must be Medicare-enrolled in an approved status to receive payment from an MA organization for health care items or services provided to a Medicare enrollee who receives their Medicare benefit through the MA organization. (For purposes of this requirement, "approved status" means the provider is neither revoked from Medicare under § 424.535 nor deactivated under § 424.540.) This includes all of the following providers:

(1) In-network and out-of-network MA providers.

(2) First-tier, downstream, and related entities (FDR) as defined at § 422.2.

(3) Providers in Health Maintenance Organizations (HMOs) or Competitive Medical Plans that contract with CMS under section 1876 of the Act.

(4) Providers participating in demonstration programs or in pilot programs.

(5) Locum tenens providers.

(6) Incident-to providers.

(b) An MA organization that does not comply with paragraph (a) of this section may be subject to sanctions under § 422.750 and termination under § 422.510.

9. Section 422.224 is amended by --

a. Revising the section heading.

b. Redesignating paragraphs (a) and (b) as new paragraphs (a)(1) and (a)(2).

c. In revised paragraph (a), adding "Before January 1, 2030-" -

d. Revising paragraph (b).

e. Adding new paragraphs (b)(1) and (b)(2).

The revisions and additions read as follows:

§ 422.224 Payment to individuals and entities excluded by the OIG, revoked from Medicare, or on the preclusion list.

* * * *

(b) Beginning January 1, 2030--

(1) An MA organization may not pay, directly or indirectly, on any basis, for items or services furnished to a Medicare enrollee by any individual or entity that is excluded by the Office of the Inspector General (OIG), revoked from Medicare under § 424.535, or on the preclusion list as described in § 423.120(c)(6) and as defined in § 423.100.

(2) If an MA organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG, revoked from Medicare under § 424.535, or on the preclusion list as described in § 423.120(c)(6) and as defined in § 423.100, the MA organization must notify the enrollee and the excluded, revoked, or precluded individual or entity, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by

the OIG, revoked from Medicare under § 424.535, or on the preclusion list as described in § 423.120(c)(6) and as defined in § 423.100.

10. Section 422.300 is revised to read as follows:

§ 422.300 Basis and scope.

This subpart is based on sections 1106, 1128J(d), 1852, 1853, 1854, and 1858 of the Act. It sets forth the requirements for making payments to MA organizations offering local and regional MA policies, including calculation of MA capitation rates and benchmarks, conditions under which payment is based on plan bids, adjustments to capitation rates (including risk adjustment), collection of risk adjustment data, conditions for use and disclosure of risk adjustment data, collection of improper payments and other payment rules. Section 422.458 specifies the requirements for risk sharing payments to MA regional organizations.

11. Section 422.310 is amended by revising paragraph (e) to read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(e) *Validation of risk adjustment data.* MA organizations and their providers and practitioners are required to submit a sample of medical records for the validation of risk adjustment data, as required by CMS. There may be penalties for submission of false data. MA organizations must remit improper payments based on RADV audits, in a manner specified by CMS in accordance with applicable HHS and CMS overpayment collection regulations. For RADV audits, CMS may extrapolate RADV Contract-Specific audit findings for payment year 2018 and subsequent payment years and may apply published payment error calculation methodologies.

(1) *RADV hardship exception requests.* An MA organization selected for a RADV audit may submit a hardship exception request if it can demonstrate that an extraordinary circumstance that prevents it from submitting required medical record documentation for the entire MA contract, a sampled enrollee's audited hierarchical condition categories (CMS-HCCs), or a

subset of audited CMS-HCCs for a given sampled enrollee. The request must be submitted in a manner, by a deadline as outlined in subregulatory guidance in advance of each payment year audit, and with supporting documentation, as prescribed by the Secretary.

(i) An MA organization is required to withdraw a specific hardship exception request before submitting it with modifications.

(ii) If an MA organization submits a valid medical record for an audited CMS-HCC(s) for which it has submitted a hardship exception request, then the hardship exception request and any decision made by CMS for the request is rendered moot.

(2) *RADV hardship exception requests documentation criteria.* An MA organization is required to submit supporting documentation with a hardship exception request that clearly demonstrates an extraordinary circumstance(s) exists and includes all relevant details required for CMS to comprehensively assess the incident or issue.

(i) Supporting documentation includes, but is not limited to, communications associated with the extraordinary circumstance and available evidence proving that the circumstance occurred.

(ii) MA organizations must pursue all potential sources of medical record documentation before submitting a hardship exception request and should review relevant record retention requirements.

(ii) MA organizations must actively pursue and submit an alternative medical record that supports an audited CMS-HCC(s) when the initial medical record sought is unavailable or insufficient to support the audited CMS-HCC(s).

(iii) An MA organization is required to submit documentation demonstrating that it sought medical record documentation from all providers associated with encounter records or other diagnosis data that the MA organization is required to submit to CMS for the purposes of receiving risk adjusted payments for sampled enrollee(s).

(3) *State requirements*. MA organizations must be aware of State requirements for

medical records to be placed in the care of a custodian for a period of time when a health care provider's office closes.

(i) If a health care provider has closed, retired, passed away, changed ownership, or otherwise undergo a change that, according to State law, should have led their medical records to be placed in the care of a custodian, MA organizations must contact the custodian to request the relevant medical records.

(ii) CMS denies a hardship request if the MA organization fails to submit sufficient supporting documentation, including documentation of the MA organization's pursuit of all possible medical record sources.

(4) *RADV hardship exception requests appeals*. A decision about whether to grant a RADV hardship exception request is final and not subject to appeal.

* * * * *

12. Section 422.311 is amended by revising paragraph (a) to read as follows:

§ 422.311 RADV audit dispute and appeal processes.

(a) *Risk adjustment data validation (RADV) audits.* In accordance with §§ 422.2 and 422.310(e), the Secretary annually conducts RADV audits to ensure risk-adjusted payment integrity and accuracy.

(1) Recovery of improper payments from MA organizations will be conducted in accordance with the Secretary's payment error calculation methodologies and recovery methodologies in accordance with applicable HHS and CMS overpayment collection regulations.

(2) CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years.

* * * * *

13. Section 422.500 is amended in paragraph (b) by adding the definition for "Credible allegation of fraud" in alphabetical order to read as follows:

§ 422.500 Scope and definitions.

* * * * *

(b) * * *

Credible allegation of fraud means an allegation from any source, including but not limited to the following:

(1) Fraud hotline tips verified by further evidence.

(2) Claims data mining.

(3) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations. Allegations are considered to be credible when they have indicia of reliability.

* * * * *

14. Section 422.501 is amended by --

a. Redesignating paragraphs (c)(1)(iv) and (2) as new paragraphs (c)(1)(iv)(A) and (c)(2)(i).

b. In new paragraphs (c)(1)(iv)(A) and (c)(2)(i), inserting the following language at the beginning of the paragraph: “Before January 1, 2030”.

c. Adding new paragraphs (c)(1)(iv)(B) and (2)(ii).

The additions read as follows:

§ 422.501 Application requirements.

* * * * *

(c) * * *

(1) * * *

(iv) * * *

(B) Beginning January 1, 2030, documentation demonstrating and verifying that payment for health care services and items is not being and will not be made to providers that are eligible to enroll in Medicare in accordance with section 1861 of the Act but that are not enrolled in Medicare in an approved status.

(2) * * *

(ii) Beginning January 1, 2030, the authorized individual must thoroughly describe how the entity and MA plan meet, or will meet, all the requirements described in this part, including providing documentation demonstrating and verifying that payment for health care services and items is not being and will not be made to providers that are eligible to enroll in Medicare in accordance with section 1861 of the Act but that are not enrolled in Medicare in an approved status.

* * * * *

15. Section 422.503 is amended by—

a. Removing paragraph (b)(4)(vi)(G)(*3*);

b. Redesignating paragraphs (b)(4)(vi)(G)(*4*) through (b)(4)(vi)(G)(*7*) as paragraphs (b)(4)(vi)(G)(*3*) through (b)(4)(vi)(G)(*6*), respectively; and

c. Revising newly redesignated paragraphs (b)(4)(vi)(G)(*3*) through (b)(4)(vi)(G)(*5*).

The revisions read as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(G) * * *

(*3*) The MA organization must have procedures to identify, and must report to CMS or its designee, any of the following in the manner described in paragraphs (b)(4)(vi)(G)(*3*) and (*4*) of this section:

(*i*) Any payment suspension implemented by an MA organization, pending investigation of credible allegations of fraud, which must be implemented in the same manner as the Secretary's requirement under section 1862(o)(1) of the Act.

(*ii*) Any information concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the MA organization related to the inappropriate prescribing of opioids.

(*iii*) Any substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste, or abuse for initiating or assisting investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners.

(*4*) The MA organization must submit data, as specified in this section, in the program integrity portal when reporting the referrals described in paragraph (b)(4)(vi)(G)(*3*) of this section. The data categories, as applicable, include referral information and actions taken by the MA organization on the referral.

(*i*) The MA organization is required to notify the Secretary, or the Secretary's designee, of a payment suspension described in paragraph (b)(4)(vi)(G)(*3*)(*i*) of this section 7 days prior to implementation of the payment suspension. The MA organization may request an exception to the 7-day prior notification to the Secretary, or the Secretary's designee, if circumstances warrant a reduced reporting time frame, such as potential beneficiary harm.

(*ii*) The MA organization is required to submit the information described in paragraphs (b)(4)(vi)(G)(*3*)(*ii*) and (*iii*) of this section, or the absence of any information, no later than January 30, April 30, July 30, and October 30 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30.

(*5*) CMS provides MA organizations with data report(s) or links to the information described in paragraphs (b)(4)(vi)(G)(*3*)(*i*) through (*iii*) of this section no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. These reports do the following:

(*i*) Include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders.

(*ii*) Are anonymized information submitted by MA organizations without identifying the source of such information.

* * * * *

16. Section 422.504 is amended by--

a. In paragraph (a)---

i. In paragraph (a)(6), removing the phrase "and the preclusion list" and adding in its place the phrase "and, before January 1, 2030, the preclusion list".

ii. Adding new paragraph (a)(22).

b. In paragraph (g)--

i. Redesignating paragraph (g)(1)(iv) as new (g)(1)(iv)(A).

ii. Adding the following language at the beginning of new paragraph (g)(1)(iv)(A): "Before January 1, 2030,".

iii. Adding new paragraph (g)(1)(iv)(B).

iv. Adding "Before January 1, 2030" at the beginning of paragraph (g)(1)(v).

c. In paragraph (i):

i. Redesignating paragraph (i)(2)(v) as new paragraph (i)(2)(v)(A).

ii. Adding the following language at the beginning of new paragraph (i)(2)(v)(A): "Before January 1, 2030,".

iii. Adding new paragraph (i)(2)(v)(B).

The additions read as follows:

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(22) Beginning January 1, 2030, to comply with the requirements of §§ 422.223 and 422.224(b).

* * *

(g) * * *

(1) * * *

(iv) * * *

(B) Beginning January 1, 2030, ensure that the enrollee does not have any financial liability for services, items, or drugs furnished, ordered, or prescribed to the enrollee by an MA contracted provider that is eligible to enroll in Medicare under section 1861 of the Act but that is not enrolled in Medicare in an approved status.

* * *

(i) * * *

(2) * * *

(v) * * *

(B) Beginning January 1, 2030, they will ensure that payments are not made to providers that are eligible to enroll in Medicare under section 1861 of the Act but are not enrolled in Medicare in an approved status.

* * * * *

17. Section 422.510 is amended by--

a. Redesignating paragraph (a)(4)(xiii) as new paragraph (a)(4)(xiii)(A).

b. Adding at the beginning of new paragraph (a)(4)(xiii)(A) the following: “Before January 1, 2030,”.

c. Adding new paragraph (a)(4)(xiii)(B).

The addition reads as follows:

§ 422.510. Termination of contract by CMS.

(a) * * *

(4) * * *

(xiii) * * *

(B) Beginning January 1, 2030, fails to meet the requirements of §§ 422.223 or 422.224(b).

* * * * *

18. Section 422.752 is amended by --

a. Redesignating paragraph (a)(13) as new paragraph (a)(13)(i).

b. Adding at the beginning of new paragraph (a)(13)(i) the following: “Before January 1, 2030,”.

c. Adding new paragraph (a)(13)(ii).

The addition reads as follows:

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) * * *

(13) * * *

(ii) Beginning January 1, 2030, fails to comply with §§ 422.223 and 422.224(b), which require the MA organization not to make payment to providers that are excluded by the OIG, revoked from Medicare under 424.535, on the preclusion list as described in § 423.120(c)(6) and as defined in § 423.100, or are eligible to enroll in Medicare under section 1861 of the Act but are not enrolled in Medicare in an approved status**.**

* * * * *

19. Section 422.2267 is amended by --

a. Revising the title of paragraph (e)(15).

b. Redesignating paragraph (e)(15) as new paragraph (e)(15)(i).

c. Adding the language “Before January 1, 2030” at the beginning of new paragraph (e)(15)(i).

d. Adding new paragraph (e)(15)(ii).

The additions read as follows:

§ 422.2267 Required materials and content.

* * * * *

(e) * * *

(15) *Excluded, revoked, or precluded provider notice.*

* * *

(ii) Beginning January 1, 2030, this is a model communications material through which plans must notify enrollees when a provider they visit or consult is excluded by the OIG, revoked from Medicare under § 424.535, on the preclusion list as described in § 423.120 and as defined in § 423.100, or is eligible to enroll in Medicare under section 1861 of the Act but is not enrolled in Medicare in an approved status.

* * * * *

PART 423 – VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

20. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w-101 through 1395w-152, and 1395hh.

21. Section 423.504 is amended by—

a. Removing paragraph (b)(4)(vi)(G)(*3*);

b. Redesignating paragraphs (b)(4)(vi)(G)(*4*) through (b)(4)(vi)(G)(*7*) as paragraphs (b)(4)(vi)(G)(*3*) through (b)(4)(vi)(G)(*5*), respectively; and

c. Revising newly redesignated paragraphs (b)(4)(vi)(G)(*3*) through (b)(4)(vi)(G)(*5*).

The revisions read as follows:

§ 423.504 General provisions.

* * * * *

(b) * * *

(4) * * *

(vi) * * *

(G) * * *

(*3*) The Part D plan sponsor must have procedures to identify, and must report to CMS or its designee, any of the following in the manner described in paragraphs (b)(4)(vi)(G)(*3*) and (*4*) of this section:

(*i*) Any payment suspension implemented by a Part D plan sponsor, pending investigation of credible allegations of fraud, which must be implemented in the same manner as the Secretary's requirement under section 1862(o)(1) of the Act.

(*ii*) Any information concerning investigations, credible evidence of suspicious activities of a provider of services (including a prescriber) or supplier, and other actions taken by the Part D plan sponsor related to the inappropriate prescribing of opioids.

(*iii*) Any substantiated or suspicious activities of a provider of services (including a prescriber) or a supplier related to fraud, waste, or abuse for initiating or assisting investigations conducted by CMS, or its designee, a Medicare program integrity contractor, or law enforcement partners.

(*4*) The Part D plan sponsor must submit data, as specified in this section, in the program integrity portal when reporting the referrals described in paragraph (b)(4)(vi)(G)(*3*) of this section. The data categories, as applicable, include referral information and actions taken by the Part D plan sponsor on the referral.

(*i*) The Part D plan sponsor is required to notify the Secretary, or the Secretary's designee, of a payment suspension described in paragraph (b)(4)(vi)(G)(*3*)(*i*) of this section 7 days prior to implementation of the payment suspension. The Part D plan sponsor may request an exception to the 7-day prior notification to the Secretary, or the Secretary's designee, if circumstances warrant a reduced reporting time frame, such as potential beneficiary harm.

(*ii*) The Part D plan sponsor is required to submit the information described in paragraph (b)(4)(vi)(G)(*3*)(*ii*) and (*iii*) of this section, or the absence of any information, no later than January 30, April 30, July 30, and October 30 of each year for the preceding periods, respectively, of October 1 through December 31, January 1 through March 31, April 1 through

June 30, and July 1 through September 30.

(*5*) CMS provides Part D plan sponsors with data report(s) or links to the information described in paragraphs (b)(4)(vi)(G)(*3*)(*i*) through (*iii*) of this section no later than April 15, July 15, October 15, and January 15 of each year based on the information in the portal, respectively, as of the preceding October 1 through December 31, January 1 through March 31, April 1 through June 30, and July 1 through September 30. These reports do all of the following:

(*i*) Include administrative actions, pertinent information related to opioid overprescribing, and other data determined appropriate by the Secretary in consultation with stakeholders.

(*ii*) Are anonymized information submitted by Part D plan sponsors without identifying the source of such information.

* * * * *

PART 424 – CONDITIONS FOR MEDICARE PAYMENT

22. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

23. Section 424.57 is amended by—

a. In paragraph (a), revising the definition of "sufficient evidence";

b. Revising paragraph (c)(11);

c. Adding paragraphs (c)(31) and (32);

d. Revising paragraph (d)(5); and

e. Adding paragraphs (d)(16) and (i).

The revisions and additions read as follows:

§ 424.57 Special payment rules for items furnished by DMEPOS suppliers and issuance of DMEPOS supplier billing privileges.

* * * * *

(a) * * *

Sufficient evidence means that CMS has furnished documentation to the surety that

establishes all of the following:

(1) The amount and basis of the overpayment, CMP, or assessment that the DMEPOS supplier owes.

(2) It is an unpaid claim.

(3) A valid surety bond exists.

(4) The request to the surety for payment satisfies the surety bond requirements, specifically--

(i) When a bond is in effect, that the unpaid claim, CMP, or assessment occurred during the term of the bond; or

(ii) When the DMEPOS supplier fails to furnish a bond, submit a rider when required, or if the DMEPOS supplier's billing privileges are revoked, that the unpaid claims, CMPs, or assessments are asserted or imposed against the DMEPOS supplier during the 2 years following, and they are based on overpayments or other events that took place during the term of the bond or rider.

* * * * *

(c) * * *

(11)(i) Must agree that neither the supplier nor third-party entities acting as agents for the DMEPOS supplier (agent) shall contact a beneficiary when supplying a Medicare-covered item by telephone call or message, including text messages, unless one of the following applies:

(A) The individual has given written permission to the supplier to contact them concerning the furnishing of a Medicare-covered item that is to be rented or purchased.

(B) The supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item.

(C) If the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier or

agent makes such contact.

(ii) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to other, dissimilar circumstances.

* * * * *

(31)(i) Must agree that neither the supplier nor third-party entities acting as agents for the DMEPOS supplier (agent) shall contact a beneficiary when supplying a Medicare-covered item using direct messages from social media platforms, email messages without opt-out features, or door-to-door in-person solicitation unless one of the following applies:

(A) The individual has given written permission to the supplier to contact them concerning the furnishing of a Medicare-covered item that is to be rented or purchased.

(B) The supplier has furnished a Medicare-covered item to the individual and the supplier is contacting the individual to coordinate the delivery of the item.

(C) If the contact concerns the furnishing of a Medicare-covered item other than a covered item already furnished to the individual, the supplier has furnished at least one covered item to the individual during the 15-month period preceding the date on which the supplier or agent makes such contact.

(ii) *Severability.* Any provision of this section held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be severable from this section and shall not affect the remainder thereof or the application of the provision to persons not similarly situated or to other, dissimilar circumstances.

(32) DMEPOS suppliers must have a process for obtaining prior beneficiary consent for items the supplier sends to the beneficiary at their home or residence. For purposes of this standard--

(i) The standard only applies to the initial order the supplier receives, not to refills; and.

(ii) The process must, at a minimum, include the following:

(A) After receiving a valid order for the item from the ordering or prescribing provider or supplier, the DMEPOS supplier must telephone or e-mail the beneficiary (or, if applicable, their representative (such as a caretaker or guardian)) and ask whether the beneficiary or representative is aware of the order or prescription, whether the beneficiary needs the item, and consents to receiving the item. The item cannot be delivered until these three conditions are met, even if the beneficiary or representative cannot be reached. If only the representative can satisfy the three conditions, the supplier's process must include a means of confirming that this individual is authorized to act on the beneficiary's behalf.

(B) For each such item, the supplier must document all of the following in a written log:

(*1*) The beneficiary's or representative's name and either their phone number or e-mail address (whichever means of communication was used).

(*2*) Time(s) and date(s) of the contact(s).

(*3*) A statement that all the conditions in paragraph (c)(32)(ii)(A) were met.

* * * * *

(d) * * *

(5) * * * *

(ii) The bond must provide the following:

(A) The surety is liable for unpaid claims, CMPs, or assessments that occur during the term of the bond**.**

(B) The surety agrees not to challenge or dispute the amount CMS determines is owed from the obligor, the underlying calculations, or the basis for overpayment.

(C) The surety must make payment to CMS as required under the bond and this paragraph (d) regardless of whether the obligor has available options to appeal, or pending appeals of, the overpayment, CMP, or assessment.

* * * * *

(16)(i) CMS may decline to accept DMEPOS supplier surety bonds from an authorized

surety (as defined in paragraph (a) of this section) under paragraph (d) of this section if the "for cause" standard in paragraph (d)(16)(ii) and the written notice and opportunity for rebuttal requirements of paragraph (d)(16)(iii) are met.

(ii) CMS' declination to accept DMEPOS supplier surety bonds from an authorized surety must be "for cause." For purposes of paragraph (d)(16)—

(A) "For cause" is when a surety under paragraph (d) has not paid or satisfied an administratively final DMEPOS supplier surety bond obligation that is owed to CMS.

(B) A DMEPOS supplier surety bond obligation becomes administratively final under paragraph (d) when—

(1) CMS has furnished sufficient evidence (as defined in paragraph (a) of this section) to the surety of its obligation to make payment under the surety bond; and

(2) The surety fails to make the required payment within 30 calendar days of receiving notice from CMS or its contractor to do so.

(iii) CMS sends written notice to the surety via certified mail of its intention to decline to accept DMEPOS supplier surety bonds from the surety. The notice must do all of the following:

(A) State the intention of CMS to decline bonds underwritten by the surety.

(B) List the reason(s) or cause for CMS' intention, including identifying the instance(s) in which the surety failed to make required payment(s).

(C) Explain the surety's rebuttal rights.

(D) Provide the surety with a 30-day opportunity to cure the stated reasons or cause.

(iv)(A)*(1)* After receiving the notice described in paragraph (d)(16)(iii) of this section, the surety has 30 calendar days from the date of the notice to submit a rebuttal to CMS' intention to decline to accept DMEPOS supplier surety bonds from the surety.

(2) CMS may, at its discretion, extend the 30-day time-periods referenced in paragraph (d)(16)(iv)(A)*(1)* of this section.

(B) A rebuttal submitted in accordance with paragraph (d)(16)(iv) of this section must

meet all of the following:

(1) Be in writing.

(2) Specify all facts or issues with which the surety disagrees with CMS' intention to decline to accept surety bonds.

(3) Submit all documentation the surety wants CMS to consider in its review of the rebuttal.

(4) Be submitted in the form of a letter that is signed and dated by one of the following:

(i) The surety's chief executive officer, chief operating officer, general partner, or equivalent official who is a W-2 employee of the surety with the authority to legally and financially bind the surety to Federal and State laws.

(ii) A representative (as defined in 42 CFR 498.10). If the legal representative is an attorney, the attorney must include a statement that he or she has the authority to represent the surety; this statement is sufficient to constitute notice of such authority. If the legal representative is not an attorney, the surety must file with CMS written notice of the appointment of a representative; this notice of appointment must be signed and dated by, as applicable, the official in paragraph (d)(16)(iv)(B)(*4)(i*) of this section or a legal representative.

(C)(*1*) The surety's failure to submit a rebuttal that is both timely under paragraph (d)(16)(iv)(A) of this section and fully compliant with all the requirements of paragraph (d)(16)(iv)(B) of this section constitutes a waiver of all rebuttal rights under this section.

(*2*) If the surety fails to submit a timely, compliant rebuttal, CMS issues a subsequent written determination that it will not accept bonds underwritten by the surety and states the declination's effective date, which would not be before the date of this written determination.

(D) Upon receipt of a timely and compliant rebuttal, CMS reviews the rebuttal to determine whether to proceed with its intended declination of surety bonds from the surety.

(E) After its receipt of any submitted rebuttal, CMS notifies the surety in writing of all of the following:

(1) Its review of the rebuttal.

(2) Its decision as to whether to proceed with its intended declination to accept DMEPOS surety bonds from the surety and the basis for that decision.

(3) If applicable, the effective date of the declination, which must not be before the date of the written notice described in this paragraph (d)(16)(iv)(E) of this section.

(F) A determination made under paragraph (d)(16)(iv)(E) of this section is not an initial determination under § 498.3(b), and, therefore, is not appealable under 42 CFR 498.5.

(v)(A) The surety has 30 days to cure the stated reasons or cause for CMS' intention to decline to accept the surety's bonds. CMS may, at its discretion, extend this 30-day period.

(B)(*1*) The surety, within the required timeframe, must submit written proof that it has cured all the deficiencies in question. This proof could include, for example, documentation that it has fully paid or satisfied all outstanding financial obligations forming the bases of CMS' intended declination.

(*2*) CMS decides whether the submitted written proof is adequate and whether all deficiencies have been corrected. If the surety submitted a timely and compliant rebuttal, CMS includes this decision in the rebuttal decision letter described in paragraph (d)(16)(iv). If the surety does not submit a timely and complete rebuttal, CMS includes its decision in a final letter to the surety confirming whether CMS will decline to accept surety bonds issued by the surety.

(vi)(A) CMS maintains on its website a publicly available list of sureties from which CMS does not accept DMEPOS supplier surety bonds under paragraph (d) of this section. This list is updated as needed.

(B)(*1*) CMS, at its discretion, may at any time remove a surety from the list described in paragraph (d)(16)(vi)(A) of this section.

(*2*) CMS notifies the surety in writing of the removal from the list and the effective date of the removal as established by CMS.

* * * * *

(i) All DMEPOS suppliers must report on the Form CMS-855S application (or its successor form), in a complete and accurate manner (including any documentation requested by CMS under § 424.510(d)(2)(iii)(C) to verify or explain the furnished information), all domestic and foreign entities and individuals that meet any of the following:

(1) Perform any marketing service of any type for the supplier.

(2) Furnish DMEPOS items or services to beneficiaries on the supplier's behalf, such as fulfillment companies.

(3) Are wholesalers from which the supplier purchases DMEPOS items for provision to the supplier's beneficiaries.

24. Section 424.58 is amended in paragraph (e) by revising paragraph (8)(i)(A) to read as follows:

§ 424.58 Accreditation.

* * * * *

(e) * * *

(8) * * *

(i) * * *

(A)*(1)* Perform a survey of all DMEPOS supplier locations for which the supplier seeks accreditation or reaccreditation with the DMEPOS accrediting organization. This includes, but is not limited to, accreditations for a new item type the supplier has not previously furnished or as required under § 424.551.

(2) Regardless of whether the accredited DMEPOS supplier is seeking accreditation or reaccreditation with the DMEPOS accrediting organization, perform a survey of the supplier location if the supplier:

(*i*) Undergoes a change in majority ownership. For purposes of this section only, a *change in majority ownership* occurs when an individual or organization acquires more than a 50 percent direct ownership interest in a DMEPOS supplier (including through the cumulative effect

of asset sales, stock transfers, consolidations, or mergers), irrespective of whether the ownership change occurred more than 36 months after the supplier's initial enrollment or its most recent change in majority ownership or the supplier qualifies for an exception under § 424.551(c); or

(*ii*) Changes its practice location.

* * * * *

25. Section 424.205 is amended by revising paragraph (c)(5) to read as follows:

§ 424.205 Requirements for Medicare Diabetes Prevention Program suppliers.

* * * * *

(c) * * *

(5) The MDPP supplier must report to its Medicare fee-for-service contractor via the enrollment application any change in its enrollment information within 30 calendar days of the change.

* * * * *

26. Section 424.510 is amended by

revising paragraphs (d)(2)(ii)(C)

to read as follows:

§ 424.510 Requirements for enrolling in the Medicare program

* * * * *

(d) * * *

(2) * * *

(ii) Submission of all documentation required by CMS under this or other statutory or regulatory authority, or under the Paperwork Reduction Act of 1995, to uniquely identify the provider or supplier.

(A) This documentation may include, but is not limited to, proof of the legal business name, practice location, social security number (SSN), tax identification number (TIN), National Provider Identifier (NPI) (if issued), and owners and managing employees of the business.

(B) Specific identification verifying documents that CMS may require include, but are not limited to, copies of the provider's, supplier's, owner's, or managing employee's driver's license, passport, social security card, birth certificate, or similar documentation.

(C) Any other documentation needed to verify and confirm the information furnished on the enrollment application. This includes, but is not limited to, documentation regarding the provider's or supplier's domestic or foreign ownership or management.

* * * * *

27. Section 424.516 is amended by revising paragraphs (d) and (e).

The revisions read as follows:

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(d) *Reporting requirements for all other provider and supplier types.* All changes in enrollment information must be reported to the Medicare-fee-for-service contractor within 30 calendar days of the change.

(e) *Special air ambulance supplier reporting requirements*. Within 30 days of any revocation or suspension of a Federal or State license or certification including Federal Aviation Administration certifications, an air ambulance supplier must report a revocation or suspension of its license or certification to the applicable Medicare contractor. The following FAA certifications must be reported:

(1) Specific pilot certifications including but not limited to instrument and medical certifications.

(2) Airworthiness certification.

* * * * *

28. Section 424.530 is amended by–

a. Revising paragraph (a)(6)(ii)(C)

b. Removing paragraph (a)(7)(iii);

c. Revising paragraphs (a)(12), (14)(i), (15)(i), and (17);

d. Adding paragraphs (a)(23) through (27);

The revisions and additions read as follows:

§ 424.530 Denial of enrollment in the Medicare program.

(a) * * *

(6) * * *

(ii) * * *

(C) CMS determines that the uncollected debt poses an undue risk of fraud, waste, or abuse.

* * * * *

(12) *Revoked under different name, numerical identifier or business identity.* The provider or supplier is currently revoked under a different name, numerical identifier, or business identity, and the applicable reenrollment bar period has not expired.

* * * * *

(14) * * *

(i) The provider or supplier – or any owner, managing employee, or managing organization thereof – is currently terminated or suspended (or otherwise barred) from participation in a State Medicaid program or any other Federal health care program, or the provider's or supplier's license is currently revoked or suspended (or voluntarily surrendered in lieu of further action) in a State other than that in which the provider or supplier is enrolling.

* * * * *

(15) * * *

(i) The physician or other eligible professional (as that term is defined in 1848(k)(3)(B) of the Act) has been subject to prior action from a State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent

governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm.

* * * * *

(17) *False Claims Act (FCA).* The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the FCA (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

* * * * *

(23) *High-Risk based on excess providers in area.* CMS determines that the provider's or supplier's enrollment presents a high risk of fraud, waste, or abuse due to the provider's or supplier's location within a limited geographic area that has an excessive number of providers and suppliers.

(24) *Change in hospice administrator.* CMS may deny a hospice's enrollment if the hospice changes its administrator within 36 months after its initial enrollment or its most recent change in administrator.

(25) *Owning or managing party.* The provider or supplier has a domestic or foreign owner, managing employee, managing organization, partner (general or limited), officer, or director--

(i) Whose identity or location cannot be confirmed; or

(ii) That CMS determines poses a risk of fraud, waste, or abuse to Medicare.

(26) *DMEPOS supplier undue risk relationship.* CMS determines that any entity or individual reported in accordance with § 424.57(i) - or the relationship or business arrangement the entity or individual has with the supplier – poses an undue risk of fraud, waste, or abuse, or of beneficiary harm.

(27) *Denial under § 424.536* - CMS determines that a denial is warranted under

§ 424.536.

* * * * *

29. Section 424.535 is amended by--

a. Revising paragraphs (a)(7), (9), (12)(i), (14), (15), (17)(i), (18), (20), (21), (22)(i);

b. Adding paragraphs (a)(26) through (a)(32).

c. Revising paragraph (c)(3);

d. Adding paragraphs (g)(1)(xxvii) through (xxxiii); and

e. Revising paragraphs (i) and (j)(1).

The revisions and additions read as follows:

§ 424.535 Revocation of enrollment in the Medicare program.

* * * * *

(a) * * *

(7) *Improper activity.* The provider or supplier engages in improper activity related to its Medicare enrollment, any billing number or identifier, or EFT arrangement.

* * * * *

(9) *Failure to report*. The provider or supplier did not comply with the reporting requirements specified in § 424.516(d) or (e), § 410.33(g)(2) of this chapter, or § 424.57(c)(2).

* * * * *

(12) * * *

(i) The provider or supplier is terminated, revoked or otherwise barred from participation in a State Medicaid program or any other Federal health care program.

* * *

(14) *Improper prescribing practices*. CMS determines that the physician or eligible professional has a pattern or practice of prescribing Medicare-covered drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries or both, or fails to meet Medicare requirements.

* * * * *

(15) *False Claims Act (FCA).* The provider or supplier, or any owner, managing employee or organization, officer, or director of the provider or supplier, has had a civil judgment under the FCA (31 U.S.C. 3729 through 3733) imposed against them within the previous 10 years.

* * * * *

(17) * * *

(i) The provider or supplier failed to repay a debt that CMS appropriately referred to the United States Department of Treasury.

* * * * *

* * * * *

(18) *Revoked under different name, numerical identifier or business identity.* The provider or supplier is currently revoked under a different name, numerical identifier, or business identity, and the applicable reenrollment bar period has not expired.

* * * * *

(20) *Billing from non-compliant location.* CMS may revoke a provider's or supplier's Medicare enrollment or enrollments, even if all of the practice locations associated with a particular enrollment comply with Medicare enrollment requirements, if the provider or supplier billed for services performed at or items furnished from a location that it knew or should have known did not comply with Medicare enrollment requirements.

* * * * *

(21) *Abusive ordering, certifying, referring, or prescribing of Part A or B services, items or drugs.* The physician or eligible professional has a pattern or practice of ordering, certifying, referring, or prescribing Medicare Part A or B services, items, or drugs that is abusive, represents a threat to the health and safety of Medicare beneficiaries, or otherwise fails to meet Medicare requirements.

(22) * * *

(i) The physician or other eligible professional (as that term is defined in 1848(k)(3)(B) of the Act) has been subject to prior action from a State oversight board, Federal or State health care program, Independent Review Organization (IRO) determination(s), or any other equivalent governmental body or program that oversees, regulates, or administers the provision of health care with underlying facts reflecting improper physician or other eligible professional conduct that led to patient harm.

* * * * *

(26) *Same suite.* The provider's or supplier's practice location is in the same suite or office as another provider or supplier whose Medicare enrollment has been revoked or denied under § 424.535 or § 424.530.

(27) *Hospice medical director or administrator.* A hospice's enrollment may be revoked if any of the following apply:

(i) The hospice's medical director is either of the following:

(A) The medical director of multiple other hospices.

(B) Practices at such a distance (for example, in a different State) from the enrolling hospice that the medical director cannot realistically perform all medical director functions required under 42 CFR Part 418.

(ii) The hospice's administrator is either of the following:

(A) The administrator of multiple other hospices.

(B) Located at such a distance from the enrolling hospice that the administrator cannot realistically perform all administrator functions required under 42 CFR part 418.

(iii) The hospice's medical director does not have an active physician medical license in the State in which they are practicing.

(28) *Change in hospice administrator.* CMS may revoke a hospice's enrollment if the hospice changes its administrator within 36 months after its initial enrollment or its most recent

change in administrator.

(29) *DMEPOS item or service.* CMS may revoke a physician's or practitioner's enrollment if the individual ordered a DMEPOS item or service that was not reasonable or necessary.

(30) *Owning or managing party.* The provider or supplier has a domestic or foreign owner, managing employee, managing organization, partner (general or limited), officer, or director:

(i) Whose identity or location cannot be confirmed; or

(ii) That CMS determines poses an undue risk of fraud, waste, or abuse to Medicare.

(31) *Supplier undue risk relationship.* CMS determines that any entity or individual reported in accordance with § 424.57(i) - or the relationship or business arrangement the entity or individual has with the supplier – poses an undue risk of fraud, waste, or abuse, or of beneficiary harm.

(32) *Revocation under § 424.536* - CMS determines that a revocation is warranted under § 424.536.

* * * * *

(c) * * *

(3) CMS may impose a reenrollment bar of up to 20 years on a provider or supplier if the provider or supplier is being revoked from Medicare for the second time.

* * * * *

(g) * * *

(1) * * *

(xxvii) For revocations under paragraph (a)(27), the date on which CMS determines that the hospice should be revoked under this paragraph.

(xxviii) For revocations under paragraph (a)(28), the date on which CMS determines that the hospice should be revoked under this paragraph.

(xxix) For revocations under paragraph (a)(29), the date on which CMS determines that the supplier should be revoked under this paragraph.

(xxx) For revocations under paragraph (a)(30), the date on which CMS determines that the provider or supplier should be revoked under this paragraph.

(xxxi) For revocations under paragraph (a)(31), the date on which CMS determines that the supplier should be revoked under this paragraph.

(xxxii) For revocations under paragraph (a)(32), the date on which CMS determines that the provider or supplier should be revoked under this paragraph.

(xxxiii) For revocations under paragraph (a)(26), the date of which CMS determines that the provider or supplier should be revoked under this paragraph.

* * * * *

(i) If a provider's or supplier's Medicare enrollment is revoked under paragraph (a) of this section, CMS may revoke any and all of the provider's or supplier's Medicare enrollments, including those under different names, numerical identifiers or business identities and those under different types.

(j) * * *

(1) CMS may revoke a provider's or supplier's Medicare enrollment if CMS determines that the provider or supplier voluntarily terminated its Medicare enrollment in order to avoid a revocation under paragraph (a) of this section that CMS would have imposed had the provider or supplier remained enrolled in Medicare.

* * * * *

30. Adding § 424.536 to read as follows:

§ 424.536 Parties in a change in majority ownership.

(a) Denial or revocation. CMS may, as applicable to the situation, deny or revoke the enrollment of any provider or supplier involved in a change in majority ownership if CMS determines--

(1) The seller, the buyer, or any provider or supplier involved in the change in majority ownership failed to comply with Medicare enrollment requirements; or

(2) The change in majority ownership, the seller, the buyer, or any provider or supplier involved in the change of majority ownership poses an undue risk of fraud, waste, and abuse to the Medicare program.

(b) *Applicability.* CMS may deny or revoke enrollment under paragraph (a) of this section regardless of whether the provider's or supplier's name, identity, or location changes due to the change in majority ownership.

(c) *Change in majority ownership defined*. For purposes of this section only, a change in majority ownership--

(1) Occurs when an individual or organization acquires more than a 50 percent direct ownership interest in a provider or supplier. This includes acquiring majority ownership through the cumulative effect of asset sales, stock transfers, consolidations, or mergers.

(2) Applies regardless of--

(A) The provider or supplier type involved;

(B) Whether the change in majority ownership occurred within 36 months of either initial enrollment or the provider's or supplier's most recent change in majority ownership; or

(C**)** Whether the change in majority ownership requires a new, initial enrollment.

(d) *Relation to other change in majority ownership provisions*. Nothing in this section affects the requirement that an HHA, hospice, or DMEPOS supplier enroll as a new provider or supplier and be surveyed/accredited if § 424.550(b) or § 424.551 applies.

***** ***** ***** ***** *****

PART 431 – STATE ORGANIZATION AND GENERAL ADMINISTRATION

31. The authority citation for part 431 is revised to read as follows:

Authority: 42 U.S.C. 1302.

§§431.800 through 431.820 will be phased out

32. Sections 431.800 through 431.820 will be phased out over a 3-year period.

33. Section 431.992 is amended by--

a. Revising paragraphs (a) and (b)(3)(ii)(E);

b. Adding paragraphs (b)(3)(ii)(F); and

c. Revising paragraphs (c) and (e) introductory text.

The revisions and additions read as follows:

§ 431.992 Corrective action plan.

(a) The State must develop a combined corrective action plan for Medicaid and CHIP for each improper payment rate measurement, designed to reduce improper payments in each program based on its analysis of the improper payment causes in the FFS, managed care, and eligibility components.

(1) The corrective action plan must address all errors that are included in the State improper payment rate defined at §431.960(f) and all deficiencies.

(2) * * *

(3) The State must identify whether each error, deficiency and corrective action plan element required under paragraph (a) and (b) of this section applies to Medicaid, CHIP, or both programs.

(b) * * *

(3) * * *

(ii) * * *

(E) A monitoring plan to monitor the progress of implementation of the corrective action.

(F) A plan for evaluating the effectiveness of each corrective action that includes at a minimum the--

(1) Number of samples used for each evaluation; and

(2) Frequency of each evaluation.

(c) Submission, CMS approval, revision, deemed disapproval, and implementation.

(1) Initial submission and CMS approval.

(i) No later than 90 calendar days after the date on which the State's Medicaid and CHIP improper payment rates are posted to the CMS contractor's website, the State must submit to CMS for approval the corrective action plan developed under this section and begin implementing each corrective action in accordance with the implementation schedule required under paragraph (b)(3) of this section.

(ii) The State must obtain CMS approval of each applicable portion of the combined corrective action plan. CMS separately reviews the Medicaid and CHIP portions and, within each program, the eligibility and non-eligibility (FFS and managed care portions). CMS approves each portion of the corrective action plan that meets the requirements of paragraphs (a) and (b) of this section and will approve or disapprove each portion separately.

(2) CMS review, revision, and disapproval.

(i) *Initial notice*. If CMS determines that a corrective action plan or any portion does not meet the criteria in paragraphs (a) and (b) of this section, CMS notifies the State in writing of the affected portion, the unmet requirements, the information or revisions needed, and the revision deadline. CMS limits requests for additional information or revisions to those necessary to address the identified issues and determine whether the affected portion meets the applicable requirements of paragraphs (a) and (b) of this section. The notice describes the approval and disapproval procedures applicable to that portion, including, for an eligibility portion, the deemed-disapproval rule and pending-review exception in paragraph (c)(2)(iii) of this section.

(ii) *Revision period*. The State must submit revisions that address the identified issues and meet the applicable requirements of paragraphs (a) and (b) of this section within 90 calendar days after the date of CMS' initial written notice under paragraph (c)(2)(i) of this section for the affected portion. A revised submission does not restart that period. CMS works with the State during the revision period and communicates in writing any remaining issues identified through its review. A timely revised eligibility portion remaining under review at the revision deadline is

subject to paragraph (c)(2)(iii)(B) of this section.

(iii) *Eligibility portions*.

(A) *Deemed disapproval*. Except as provided in paragraph (c)(2)(iii)(B) of this section, each affected eligibility portion not approved by the end of the revision period will be deemed disapproved for the applicable PERM-review year, without a separate written disapproval determination. Following a deemed disapproval, the State must continue to address the identified issues and seek CMS approval of a revised eligibility portion that meets the applicable requirements of paragraphs (a) and (b) of this section. CMS' subsequent written approval supersedes the earlier deemed disapproval of that portion for the applicable PERM review year, as provided in paragraph (c)(2)(v) of this section.

(B) *Pending review*. An eligibility portion is not deemed disapproved while CMS review of the most recent revision submitted within the revision period remains pending. CMS provides written status communication when that review remains pending at the revision deadline. This exception applies whether or not CMS has issued the status communication by that deadline. The notice neither approves nor disapproves the portion.

(C) *Determination after pending review*. Upon completion of the review that remained pending under paragraph (c)(2)(iii)(B) of this section after the revision deadline, CMS approves the eligibility portion if it meets the applicable requirements of paragraphs (a) and (b) of this section. Otherwise, CMS issues a written disapproval identifying the unmet requirements. The disapproval takes effect when CMS issues the notice and is not effective retroactively at the revision deadline.

(iv) *Non-eligibility portions*. The provisions in paragraph (c)(2)(iii) of this section does not apply to non-eligibility portions. After the revision period and completion of its review, CMS issues a written disapproval identifying the unmet requirements for a non-eligibility portion that does not meet the applicable requirements of paragraphs (a) and (b) of this section. The disapproval takes effect when CMS issues the notice. The approval status of a non-eligibility

portion does not determine satisfaction of the condition in § 455.804(b)(1).

(v) *Continuing obligation and later approval*. The State must continue to revise and resubmit each unapproved eligibility and non-eligibility portion until CMS approves it, including after the correction period or a deemed or written disapproval. CMS reviews subsequent submissions and approves each portion that meets the applicable requirements of paragraphs (a) and (b) of this section. CMS' written approval supersedes the prior disapproval of that portion for the applicable PERM review year. The effect of an eligibility portion's approval status, including later approval, on the PERM corrective action plan condition for a good faith waiver is governed by § 455.804(b)(1). Disapproval under this section does not, by itself, impose a Medicaid or CHIP disallowance or constitute a final good faith waiver determination.

(3) *Implementation before and after CMS review*.

(i) The State must begin implementing corrective actions within the period specified in paragraph (c)(1)(i) of this section and follow the implementation schedule in its most recently submitted, unapproved portion while CMS review is pending, including during the revision period and after a disapproval, unless CMS directs the State in writing to defer, modify, or discontinue a specific corrective action. An approved portion remains operative unless CMS approves a revision or directs a change in writing.

(ii) Upon CMS approval of a corrective action plan or a program specific portion, the State must implement the approved plan or portion and must promptly revise its implementation schedule and ongoing activities, as necessary, to conform to the approved corrective action plan or portion.

(iii) Corrective actions implemented before CMS approval count toward implementation to the extent that the actions are consistent with the approved plan or portion. Revision or disapproval of one portion does not, by itself, require the State to restart work on another portion or repeat work consistent with the approved portion.

* * * * *

(e) Semiannual eligibility updates. In addition to paragraphs (a) through (d) of this section, each State that has an eligibility improper payment rate over the allowable threshold of 3 percent for consecutive PERM years must submit updates on the status of corrective action implementation to CMS every 6 months, beginning 2 months after CMS formally approves the State's corrective action plan, and ending before CMS posts the State's eligibility improper payment rate for the next subsequent PERM cycle. Where a State's eligibility improper payment rate remains over the allowable threshold for a subsequent PERM cycle, requiring approval of a new or updated corrective action plan, the reporting window described in this paragraph (e) begins anew, two months after CMS' approval of that subsequent corrective action plan, independent of any prior reporting window. Where only the Medicaid eligibility improper payment rate or only the CHIP eligibility improper payment rate exceeds the 3 percent threshold, the State's status updates required under this paragraph (e) need only address the program that exceeds the threshold. Status updates must include, but are not limited to the following:

* * * * *

§ 431.1010 [Removed]

34. Section 431.1010 is removed effective DATE TO BE DETERMINED.

PART 438 – MANAGED CARE

35. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

36. Section 438.3 is amended by revising paragraph (c)(2) to read as follows:

§ 438.3 Standard contract requirements.

* * * * *

(c) * * *

(2) Capitation payments may only be made by the State and retained by the MCO, PIHP, or PAHP for Medicaid eligible enrollees, provided that--

(i) Following the provision of notice of action and fair hearing rights in accordance with

42 CFR 435.917 and 435.918, and part 431 subpart E, States must recover capitation payments for any payment periods following the enrollee's date of death, and may recover capitation payments for any payment periods following the date of relocation out-of-State.

(ii) The State must reimburse CMS for an amount equal to the Federal share of all capitation payments subject to recovery under paragraph (c)(2)(i) of this section, taking into account applicable differences in the Federal matching rate.

* * * * *

7. Section 438.608 is amended by revising paragraphs (a)(3) and (d)(1)(iv), redesignating paragraph (f) as paragraph (g); and adding new paragraph (f) to read as follows:

§ 438.608 Program integrity requirements under the contract.

(a) * * *

(3) Provision for notification to the State, using the State's defined procedure, within 30 calendar days of when it receives information about a change in an enrollee's circumstances that may affect their eligibility, including the following:

(i) Any change in the enrollee's address information if provided by the enrollee or verified directly with the enrollee, including both out-of-State and in-State address changes.

(ii) The death of an enrollee.

* * * * *

(d) * * *

(1) * * *

(iv) This provision does not apply to any amount of a recovery to be retained under False Claims Act cases or through other audits or investigations, which include those performed by, but not limited to, any of the following:

(A) The Federal Government, including Federal agencies, or its contractors.

(B) A State or its contractors.

* * * * *

(f) Paragraph (a)(3) of this section applies to PCCMs and PCCM entities.

* * * * *

PART 447 – PAYMENTS FOR SERVICES

37. Section 447.45 is amended by adding paragraph (f)(1)(vi) to read as follows:

§ 447.45 Timely claims payment.

(f) * * *

(1) * * *

(vi) Verification that the type of service performed, the individual receiving the service, the date of the service, the location of service delivery, the individual providing the service, and the time the service begins and ends, for services subject to the requirements of section 1903(l) of the Act and additional Medicaid services the State independently subjects to EVV, are supported by an EVV record.

PART 455 – PROGRAM INTEGRITY: MEDICAID

38. The authority citation for part 455 continues to read as follows:

Authority: 42 U.S.C. 1302.

39. Section 455.2 is amended by revising the definitions of "Credible Allegation of Fraud" and "Conviction or Convicted" to read as follows:

§ 455.2 Definitions.

* * * * *

Credible allegation of fraud. A credible allegation of fraud is an allegation that has indicia of reliability, which may come from any source.

(1) Sources include the following:

(i) Fraud hotline tips verified by further evidence.

(ii) Claims data mining.

(iii) Patterns identified through provider audits, civil false claims cases, and law enforcement investigations.

(iv) Other sources not specified in paragraphs (1)(i) through (iii) of this definition.

(v) A determination by CMS, or by another Federal agency, that an allegation of fraud against a provider is credible.

(2) Allegations are considered to be credible when they have indicia of reliability. This means that:

The State Medicaid agency has reviewed all allegations, facts, and evidence carefully and acts judiciously on a case-by-case basis. For CMS or other Federal agency determinations, a State may rely on such other agency's determination without re-verifying the underlying allegation, unless the State has specific, documented information indicating that reliance on the CMS or other Federal agency determination would be unreasonable under the circumstances.

Conviction or Convicted has the same meaning as the definition of "Convicted" in 42 CFR 1001.2.

* * * * *

40. Section 455.14 is amended by revising the paragraph to read as follows:

§ 455.14 Preliminary investigation.

(a) If the agency receives a complaint of Medicaid fraud or abuse from any source or identifies any questionable practices, it must conduct a preliminary investigation to determine whether there is sufficient basis to warrant a full investigation.

(1) For preliminary investigations of allegations of Medicaid fraud or abuse by providers involving services subject to the requirements of section 1903(l) of the Act and additional Medicaid services the State independently subjects to electronic visit verification (EVV) requirements, the State Medicaid agency must review and analyze the associated EVV records to attempt to verify the validity of the allegation or questionable practice, including whether billed services were rendered for the appropriate duration and at the appropriate location.

(2) [Reserved].

(b) {Reserved].

41. Section 455.17 is amended by revising paragraph (b) to read as follows:

§ 455.17 Reporting of fraud and abuse to the State Medicaid agency and to CMS.

* * * * *

*(*b) For cases of suspected provider fraud and abuse that the State Medicaid agency has determined warrant a full investigation, the State must report to CMS the following information:

(1) The provider's name;

(2) The provider's National Provider Identifier (NPI), or Medicaid provider identification number if the provider is ineligible to receive an NPI under applicable Federal law;

(3) The provider's Employer Identification Number or Taxpayer Identification Number (EIN/TIN), if available;

(4) The State in which the investigation is being conducted;

(5) The source of the complaint;

(6) The type of provider;

(7) The type of service involved;

(8) The nature of the complaint;

(9) The payor (for example, Medicaid Fee-For-Service or managed care);

(10) The relevant claim dates;

(11) The approximate time period covered by the investigation;

(12) The estimated overpayment amount;

(13) Where a final determination has been made, the final overpayment amount;

(14) The investigation status; and

(15) The legal and administrative disposition of the case, including the following:

(i) Actions taken by law enforcement.

(ii) Administrative actions taken by the State Medicaid agency, including provider termination, payment suspension (including good cause exceptions identified under § 455.23), and overpayment recovery status.

42. Section 455.23 is amended by -–

a. Creating subparagraph (a)(1)(i) in paragraph (a)(1);

b. Updating paragraph (d)(4) and creating subparagraphs (i), (ii), and (iii);

c. Creating subparagraph (1)(i) in paragraph (e); and

d. Updating the title of paragraph (g) and subparagraph (g)(3).

The changes read as follows:

§ 455.23 Suspension of payments in cases of fraud.

(a) * * *

(1) * * *

(i) A credible allegation of fraud may be identified by CMS or any other Federal agency. States are permitted to rely on the determination by CMS or another Federal agency that an allegation is credible.

(d) * * *

(4) If the Medicaid Fraud Control Unit (MFCU) or other law enforcement agency declines to accept the fraud referral for investigation or notifies the State agency that it has closed such an investigation without resolution of the allegation, the State agency must discontinue the payment suspension unless the State agency—.

(i) Has alternative Federal or State authority by which it may impose a suspension or makes a fraud referral to another law enforcement agency. In that situation, the provisions of paragraph (d)(3) of this section apply equally to that referral as well; or

(ii) Determines and documents in writing that the credible allegation of fraud remains under active investigation by the State Medicaid agency or by another State or Federal agency.

(iii) A suspension maintained under paragraph (d)(4)(ii) of this section is subject to the following limitations:

(A) The State Medicaid agency must, at least quarterly, redetermine and document in writing whether the credible allegation of fraud continues to be under active investigation

warranting the continuation of the payment suspension. If at any redetermination the State agency cannot make this finding, the State agency must immediately discontinue the suspension.

* * * * *

(e) *Good cause not to suspend payments.* A State may find good cause not to suspend payments—or not to continue a payment suspension already in place—to an individual or entity under investigation for a credible allegation of fraud, if any of the conditions below apply. Before forgoing or discontinuing a payment suspension based on a good cause exception under this paragraph (e) or paragraph (f), the State must evaluate and document in writing that the specific criteria for the invoked exception have been met in that individual case.

(1) * * *

(i) If the good cause exception invoked is the exception described in this paragraph (e) (1), the State must also request a certification from the MFCU or other law enforcement agency for justifications and updates pertaining to the good cause exceptions and verification that the good cause still exists.

(g) *Documentation, record retention, and reporting requirements*. State Medicaid agencies must meet the following requirements:

* * *

(3) Quarterly report to the Secretary information on each of the following:

43. Section 455.101 is amended by -–

a. Adding a definition of "Managing organization" in alphabetical order;

b. Revising the title and opening paragraph of the current definition of "Person with an ownership or control interest".

The addition and revision read as follows:

§ 455.101 Definitions.

* * * * *

Managing organization means an entity that exercises operational or managerial control

over, or that directly or indirectly conducts the day-to-day operations of, a provider, either under contract or through some other arrangement.

* * * * *

Person or organization with an ownership or control interest is one that meets any of the following:

* * * * *

44. Section 455.104 is amended by –

a. In paragraph (b)(1)(i),

i. Removing the phrase "(individual or corporation)" and adding in its place the phrase "or organization"; and

ii. Removing the phrase "for corporate entities" and adding in its place the phrase "for entities";

b. Revising paragraph (b)(1)(iii);

c. In paragraph (b)(2), removing the phrase "(individual or corporation)" and adding in its place the phrase "or organization" each time it appears;

d. Revising paragraph (b)(4); and

The revisions read as follows:

§ 455.104 Disclosure by Medicaid providers and fiscal agents: Information on ownership and control.

* * * * *

(b) * * *

(1) * * *

(iii) The tax identification number of both of the following:

(A) Any organization with an ownership or control interest in, or that serves as a managing organization of, the disclosing entity (or fiscal agent or managed care entity).

(B) Any subcontractor in which the disclosing entity has an ownership or control interest.

* * * * *

(4)(i) The name, address, date of birth, and Social Security Number of any managing employee of the disclosing entity (or fiscal agent or managed care entity).

(ii) The name, address, and tax identification number of any managing organization of the disclosing entity (or fiscal agent or managed care entity).

* * * * *

45. Section 455.106 is amended by revising paragraph (a) and removing paragraph (c) to read as follows:

§ 455.106 Disclosure by providers: Information on persons convicted of crimes.

(a) *Information that must be disclosed.* Before the Medicaid agency enters into or renews a provider agreement, or at any time upon written request by the Medicaid agency, the provider must disclose to the Medicaid agency whether the provider, any person or organization with an ownership or control interest in the provider, or an agent, managing employee or managing organization of the provider, under any current or former name, numerical identifier, or business identity meets any of the following:

(1) Was, within the preceding 10 years, convicted of a Federal or State felony offense (regardless of type).

(2) Has been convicted of a misdemeanor under Federal or State law related to--

(i) The person's or organization’s involvement with any Federal or State health care program in the previous 10 years; or

(ii) Sexual assault or financial misconduct.

(3) Has been revoked or terminated, or is currently suspended, from participation in any State Medicaid program, CHIP, Medicare or any Federal health care program.

(4) Is currently subject to a payment suspension under Medicaid, CHIP, or Medicare.

(5) Has had its health care license revoked, or whose license is currently suspended, in any State. (This includes situations where the individual or entity voluntarily surrendered the

license in lieu of disciplinary action.)

* * * * *

§ 455.107 [Amended]

46. Section 455.107 is amended by removing paragraph (g) and redesignating paragraph (h) as paragraph (g).

47. Section 455.416 is amended to read as follows:

§ 455.416 Reasons for denial or termination of enrollment.

(a) *Exclusion or debarment*. The State must deny or terminate a provider's enrollment if the provider, any person or organization with an ownership or control interest in the provider, or any managing employee or managing organization or agent of the provider, or other health care or administrative or management services personnel furnishing services payable by a Federal health care program of the provider is either of the following:

(1)(i) Excluded from the Medicare, Medicaid, and any other Federal health care programs, as defined in 42 CFR 1001.2 of this chapter, in accordance with sections 1128, 1156, 1842, 1862, 1867, or 1892 of the Act; or

(ii) Debarred, suspended, or otherwise excluded from participating in any other Federal procurement or non-procurement activity in accordance with section 2455 of the Federal Acquisition Streamlining Act (FASA).

(2) The individuals and organizations identified in paragraph (a)(1) of this section include, but are not limited to, W-2 employees and contracted individuals and organizations of the provider.

(b) *Undue risk*. The State must deny or terminate a provider's enrollment if the State, -in consultation with CMS, determines under § 455.107 that a particular affiliation poses an undue risk of fraud, waste or abuse.

(c) *Program termination*. The State must deny or terminate a provider's enrollment if the provider is terminated under title XVIII of the Act or under the Medicaid program or CHIP of

any other State and is currently included in the termination database under § 455.417.

(d) *Certain misdemeanor convictions*.

(1) The State must deny or terminate a provider's enrollment if the provider, any person or organization with an ownership or control interest in the provider, or any managing employee or managing organization of the provider, under any current or former name or numerical identifier or business identity, has been convicted in the previous 10 years of a misdemeanor under Federal or State law is related to:

(i) The person or organization's involvement with the Medicare, Medicaid, or title XXI program; or

(ii) Sexual assault or financial misconduct, and the State determines that the misdemeanor conviction is detrimental to the best interests of the Medicaid program or CHIP and its beneficiaries.

(2) The State may forgo denial or termination under paragraph (d) of this section if it determines that denial or termination of enrollment is not in the best interests of the Medicaid program or CHIP and its beneficiaries and the State documents that determination in writing.

(e) *Non-compliance.*

(1) The State must deny or terminate a provider's enrollment if the provider is non-compliant with any requirement described in subpart B or E of this part 455. Examples of non-compliance include, but are not limited to, the following:

(i) The provider or a person with an ownership or control interest or who is an agent or managing employee or managing organization of the provider fails to submit timely or accurate information or fails to cooperate with any screening requirement required under subpart B or E.

(ii) The provider, or any person with a 5 percent or greater direct or indirect ownership interest in the provider, fails to submit sets of fingerprints in a form and manner to be determined by the Medicaid agency within 30 days of a CMS or State Medicaid agency request.

(iii) The provider fails to permit access to provider locations for any site visits under §

455.432.

(iv) The State cannot verify the provider's identity.

(2) The State may forgo denial or termination under paragraph (e) of this section if it determines that denial or termination of enrollment is not in the best interests of the Medicaid program or CHIP and its beneficiaries and the State documents that determination in writing.

(f) *Felony convictions*.

(1) The State must deny or terminate a provider's enrollment if the provider, any person or organization with an ownership or control interest in the provider, or any managing employee or managing organization of the provider was, within the preceding 10 years, convicted of a Federal or State felony offense that the State determines is detrimental to the best interests of its Medicaid program or CHIP and its beneficiaries. Offenses would include, but not be limited in scope or severity to, any of the following:

(i) Felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted.

(ii) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud, and other similar crimes for which the individual was convicted.

(iii) Any felony that placed the Medicaid program or CHIP or its beneficiaries at immediate risk, such as a malpractice suit that results in a conviction of criminal neglect or misconduct.

(iv) Any felony that would result in mandatory exclusion under section 1128(a) of the Act.

(2) The State may forgo denial or termination under paragraph (f) of this section if it determines that denial or termination of enrollment is not in the best interests of the Medicaid program or CHIP and its beneficiaries and the State documents that determination in writing.

(g) *False or misleading information*.

(1) The State must deny or terminate a provider's enrollment if the provider submitted

false or misleading information to (or omitted information from) the Medicaid or CHIP program in order to gain or maintain enrollment.

(2) The State may forgo denial or termination under paragraph (g) of this section if it determines that denial or termination of enrollment is not in the best interests of the Medicaid program or CHIP and its beneficiaries and the State documents that determination in writing.

(h) *Drug Enforcement Administration Certificates.*

(1) The State must deny or terminate a physician's or practitioner's enrollment if the physician's or practitioner's Drug Enforcement Administration (DEA) Certificate of Registration to dispense a controlled substance is currently suspended or revoked or is surrendered in response to an order to show cause.

(2) The State may forgo denial or termination under paragraph (h) of this section if it determines that denial or termination of enrollment is not in the best interests of the Medicaid program or CHIP and its beneficiaries and the State documents that determination in writing.

(i) *Misuse of enrollment.* (1) The State must terminate a provider's enrollment if the provider knowingly sells to or allows another individual or entity to use its enrollment to bill Medicaid or CHIP. This does not include either of the following:

(i) Providers who enter into a valid Medicaid or CHIP assignment of payment under § 447.10(g).

(ii) When State law permits another individual or entity to bill Medicaid or CHIP under the provider's enrollment in a change of ownership situation.

(2) The State may forgo termination under paragraph (i) of this section if it determines that termination of enrollment is not in the best interests of the Medicaid program or CHIP and its beneficiaries and the State documents that determination in writing.

(j) *Improper prescribing practices.*

(1) The State must terminate enrollment if a physician or practitioner has a pattern or practice of prescribing Medicaid or CHIP drugs that meets either of the following:

(i) Is abusive or represents a threat to the health and safety of Medicaid or CHIP beneficiaries.

(ii) Fails to meet Medicaid or CHIP requirements.

(2) The State may forgo termination under paragraph (j) of this section if it determines that termination of enrollment is not in the best interests of the Medicaid program or CHIP and its beneficiaries, and the State documents that determination in writing.

(k) *Abusive ordering, certifying, or referring of Medicaid or CHIP services or items.*

(1) The State must terminate a physician's or practitioner's enrollment if the physician or practitioner has a pattern or practice of ordering, certifying, or referring Medicaid or CHIP services or items that is abusive, represents a threat to the health and safety of Medicaid or CHIP beneficiaries or otherwise fails to meet Medicaid or CHIP requirements.

(2) The State may forgo termination under paragraph (k) of this section if it determines that termination of enrollment is not in the best interests of the Medicaid program or CHIP and its beneficiaries and the State documents that determination in writing.

48. Section 455.418 is added to read as follows:

§ 455.418 State reporting of denials and terminations.

(a) *Reporting.* Each State must submit to CMS on a monthly basis – and in a format required by CMS -- the legal business and doing business names, address, tax identification number, and National Provider Identifier of each Medicaid or CHIP provider whose enrollment, within the applicable monthly period, the State:

(1) Denied or terminated under § 455.416. This must include--

(i) The regulatory basis for the denial or termination;

(ii) The facts of the case; and

(iii) An explanation of how the State reached its decision.

(2) Was required to deny or terminate under § 455.416 but declined to do so based on a best interests finding. This must include:

(i) The regulatory basis for the prospective denial or termination.

(ii) The facts of the case.

(iii) An explanation of how the State reached its decision, and reasons for the State's best interests determination.

(b) *Relationship to Termination.* The requirements of this section are in addition to, and not in lieu of, State reporting requirements under sections 1902(kk)(8) and 1902(a)(41) of the Act and apply only to denials or terminations in accordance with § 455.416.

§ 455.436 [Amended]

49. Section 455.436 is amended by –

a. In paragraph (b), removing the phrase "Excluded Parties List System (EPLS)" and adding in its place the phrase "System for Award Management (SAM)"; and

b. In paragraph (c), removing the acronym "EPLS" and adding in its place the acronym "SAM".

50. Section 455.440 is revised to read as follows:

§ 455.440 National Provider Identifier.

(a) Claims for ordered or referred services. The State Medicaid agency must require all claims for payment for items and services that were ordered or referred to contain the National Provider Identifier (NPI) of the physician or other professional who ordered or referred such items or services.

(b) General requirement. A State Medicaid agency must collect, maintain, and use the National Provider Identifier (NPI) for each provider enrolled in the State's Medicaid program that is eligible to obtain an NPI as a covered health care provider under 45 CFR part 162.

(c) Scope of use. For providers subject to paragraph (b) of this section, the State Medicaid agency must collect, maintain, and use the provider's NPI as part of--

(1) Medicaid provider enrollment and revalidation in accordance with subpart E of this part;

(2) Claims processing in accordance with § 447.45;

(3) Managed care oversight pursuant to part 438 of this chapter;

(4) Program integrity activities, including but not limited to fraud and abuse investigations and reporting in accordance with subpart A of this part; and

(5) Reporting to CMS in accordance with § 455.17 and any other applicable reporting requirements.

(d) *Consistency across systems*. The State Medicaid agency must ensure that each provider's NPI is consistently maintained and used across all Medicaid provider enrollment, claims processing, managed care oversight, program integrity, and reporting systems.

51. Section 455.450 is amended by revising its opening paragraph to read as follows:

§ 455.450 Screening levels for Medicaid providers.

A State Medicaid agency must screen all initial applications, including applications for a new practice location, and any applications received in response to a re-enrollment or revalidation of enrollment request based on a categorical risk level of "limited," "moderate," or "high." For provider types that also exist in Medicare, the State must assign such providers to the same or higher risk category applicable under Medicare in accordance with § 424.518. If a provider could fit within more than one risk level described in this section, the highest level of screening is applicable.

52. Section 455.460 is amended by –

a. In paragraph (a) introductory text removing the phrase "a prospective or re-enrolling provider other than either of the following:" and adding in its place the phrase "a prospective, revalidating or re-enrolling provider other than the following:";

b. Redesignating paragraphs (a)(2)(ii) introductory text, (a)(2)(ii)(A), and (a)(2)(ii)(B) as paragraphs (a)(2)(ii)(A) introductory text, (a)(2)(ii)(A)(*1*), and (a)(2)(ii)(A)(*2*), respectively;

c. In newly redesignated paragraph (a)(2)(ii)(A) introductory text removing the phrase "Providers that have" and adding in its place the phrase "Subject to paragraph (a)(2)(ii)(B) of

this section, providers that have"; and

d. Adding a new paragraph (a)(2)(ii)(B).

The addition reads as follows:

§ 455.460 Application fee.

(a) * * *

(2) * * *

(ii) * * *

(B) Paragraphs (a)(2)(ii)(A)(1) and (2) of this section do not apply if the State is screening the provider at a higher level under § 455.450 than the Medicare contractor or other State to which the provider paid the fee. In this situation, the State may collect a fee from the provider that represents the cost of this additional screening above and beyond the level of screening the Medicare contractor or State performed under § 455.450. However, the State shall document the reason(s) for the enhanced screening.

* * * * *

53. Adding subparts G through J to part 455 to read as follows:

Subpart G – Administrative Requirements for Program Integrity Corrective Action Plans

Sec.

455.600 Purpose.

455.602 Program integrity corrective action plans.

Subpart G: Requirements for Program Integrity Corrective Action Plans

§ 455.600 Purpose.

This subpart establishes administrative requirements governing:

(a) State Medicaid program integrity corrective action plans (CAPs).

(b) This subpart only applies to Medicaid. Corrective action and withholding for failure to comply with CHIP requirements are governed by part 457 of this chapter, including § 457.204.

§ 455.602 Program integrity corrective action plans.

(a) If CMS identifies findings of non-compliance with Medicaid statutory and regulatory requirements as a result of a CMS program integrity audit, the final audit report will specify the findings, if any, for which the State is required to develop a Program Integrity CAP. If the final audit report requires a Program Integrity CAP for one or more findings, the State must develop a single Program Integrity CAP that addresses all such findings, as described in paragraph (b) of this section.

(b) If required under paragraph (a) of this section to develop a Program Integrity CAP, the State must address each finding of non-compliance for which the final audit report requires corrective action through a Program Integrity CAP and take the following actions:

(1) Conduct a root cause analysis to identify the specific programmatic causes to which each finding of non-compliance is attributed.

(2) Identify the specific corrective action(s) that will be implemented to address each finding of non-compliance and bring the State into compliance.

(3) Develop an implementation schedule for each corrective action and implement such corrective actions in accordance with the schedule. The implementation schedule must identify all of the following for each corrective action:

(i) Status of the corrective action.

(ii) Estimated or actual implementation date.

(iii) Contact information for all key personnel responsible for implementation.

(iv) Monitoring plan to track the progress of implementation of the corrective action.

(4) A plan for evaluating the effectiveness of each corrective action and how the corrective action will rectify the finding(s) of non-compliance.

(c) If the final audit report requires a Program Integrity CAP under paragraph (a) of this section, the State must submit the CAP to CMS no later than 30 calendar days after the date of the final audit report, unless CMS grants a good-cause extension.

(1) The Program Integrity CAP developed under paragraph (a) of this section is subject to CMS approval. If CMS determines that a submitted Program Integrity CAP does not satisfy the requirements of paragraph (b) of this section, CMS returns the CAP to the State for revision and resubmission.

(2) The State must provide updates on Program Integrity CAP implementation progress at each milestone timeframe identified in the implementation schedule for each corrective action under paragraph (b)(3) of this section, and upon request by CMS. Such updates must include the State's progress in implementing the corrective action in accordance with the approved implementation schedule and the evaluation of the effectiveness of the corrective action and how the corrective action is rectifying the finding or findings of non-compliance under paragraph (b)(4) of this section.

(d) Nothing in this section limits, delays, or conditions CMS' exercise of any other administrative or financial action otherwise authorized under Federal law. CMS may pursue such action before, concurrently with, or after requiring a Program Integrity CAP under this section, as appropriate.

Subpart H – Medicaid and CHIP Beneficiary Eligibility Audit Program

Sec.

455.700 Basis and scope.

455.702 Definitions.

455.704 General requirements.

455.706 Audit methods for audits with findings potentially subject to disallowance.

455.708 Protection of applicant and beneficiary information and due process rights.

455.710 Access to records.

455.712 Corrective action plans.

Subpart H – Medicaid and CHIP Beneficiary Eligibility Audit Program

§ 455.700 Basis and scope.

This subpart establishes requirements for Medicaid and CHIP beneficiary eligibility audits designed to reduce eligibility errors by reviewing States' eligibility processes and policies, and the appropriateness of eligibility determinations for sampled cases. A State is required to participate in an eligibility audit when selected by CMS, as set forth in this subpart. The statutory bases for this subpart are sections 1903(u), 2105(e), and 1936 of the Act.

§ 455.702 Definitions.

For purposes of this subpart, the following terms have the definitions:

Corrective action means a specific action that a State would be required to implement to address identified eligibility errors to achieve compliance with Federal requirements and Medicaid and CHIP State plans (or waiver of such plans).

Eligibility means meeting the State's categorical, financial, and non-financial criteria for receipt of benefits under the Medicaid or CHIP programs.

Eligibility audit means a CMS and Federal contractor conducted, primarily risk-based audit of States' Medicaid and CHIP point of application or renewal eligibility determinations, designed to verify compliance with Federal and State eligibility requirements, reduce eligibility errors, and assist States in improving their eligibility determination processes.

Eligibility determination has the same meaning as at § 435.4 for Medicaid, and § 457.301 for CHIP.

Eligibility error means an error resulting from the State's improper application of Federal or State requirements, causing an improper determination of a beneficiary's eligibility. For purposes of this definition, an eligibility error could include, but would not be limited to, authorizing an ineligible individual as eligible when they received services, providing certain ineligible services to an otherwise eligible individual, improperly denying an individual's Medicaid or CHIP application, improperly terminating a beneficiary from Medicaid or CHIP, or enrolling in managed care an individual ineligible for managed care.

Erroneous excess payments for medical assistance means the total of payments under the

State plan (or waiver of such plan) with respect to ineligible individuals and families, and overpayments on behalf of eligible individuals and families by reason of errors in determining the amount of expenditures for medical care required of an individual or family as a condition of eligibility.

Observation means an instance where a beneficiary's or applicant's eligibility was correctly determined notwithstanding the State failing to follow Federal and State eligibility requirements.

§ 455.704 General requirements.

(a) When selected, a State must participate in a Medicaid and CHIP beneficiary eligibility audit upon written notification by CMS of an audit. In rare cases, CMS may grant a State an audit exemption for demonstrating extraordinary circumstances beyond the State agency's control that make audit participation impracticable during the applicable fiscal year audit period.

(1) Audit selection criteria include all of the following:

(A) Every State will undergo a Medicaid and CHIP beneficiary eligibility audit at least once every 5 years.

(B) In selecting States for audit, CMS prioritizes States determined to be at high-risk for eligibility errors.

(2) CMS issues an engagement letter to the relevant State Medicaid director, outlining the audit objectives, scope, applicable disallowance authorities, data and documentation request and corresponding data and documentation submission due dates.

(b) State participation during an eligibility audit includes the following:

(1) Providing the requested eligibility and enrollment data and documentation within 10 business days from the date the engagement letter was issued, unless granted an extension by CMS.

(2) Assigning at least two State subject matter experts to navigate the necessary information contained in the State's eligibility and enrollment systems in coordination with the

auditors during the case review portion of the audit to allow CMS to verify if eligibility determinations were made in accordance with Federal and State requirements for the sampled cases.

(3) Providing requested copies of additional eligibility case records and any other necessary documentation for sampled cases and documentation within 5 business days of the written request unless granted an extension by CMS.

(4) Responding to the draft report within 10 business days, unless granted an extension by CMS, by providing a written response that indicates whether the State agrees or disagrees with each eligibility error. For any eligibility error with which the State disagrees, the State must provide a detailed written explanation of the basis for disagreement and submit supporting documentation to CMS to substantiate its position.

(5) Submitting a CAP to CMS for approval with proposed corrective actions to address each eligibility error, if applicable, by the deadline specified in the final audit report.

§ 455.706 Audit methods for audits with findings potentially subject to disallowance.

(a) The audit will include four statistically valid stratified random samples of Medicaid and CHIP beneficiaries selected from the universes of eligibility and enrollment data provided by the State. Samples are selected from all eligibility categories included in the Medicaid and CHIP programs.

(1)(i) One sample includes individuals who are enrolled in Medicaid whose eligibility was determined or redetermined and for whom the State made payments for services provided during the full fiscal year audit year.

(ii) The second sample include individuals whose Medicaid eligibility was denied or terminated during the full fiscal year audit period.

(iii) The third sample consists of individuals enrolled in CHIP whose eligibility was determined or redetermined and for whom the State made CHIP payments for services provided during the audit period.

(iv) The fourth sample consists of individuals whose CHIP eligibility was denied or terminated during the audit period.

(2) The State's Medicaid and CHIP information systems will be used to obtain data on beneficiaries and applicants in the sampling frames and their associated Medicaid and CHIP payments.

(3) A statistical software package would be used to generate random numbers to select samples from each stratum.

(4) Sample sizes will be designed to support statistically valid extrapolations of individuals associated with eligibility errors and their associated improper payments at a 90 percent confidence level, if applicable.

(b) The total number of individuals associated with eligibility errors extrapolated to the State's entire Medicaid and CHIP populations and the total extrapolated amount of erroneous excess payments made on behalf of individuals who were improperly enrolled in Medicaid or CHIP during the audit period will be estimated based on the lower limit of the 90 percent confidence interval, if applicable, using statistical software.

(c) Extrapolated error rates for the total dollar amount attributable to erroneous excess payments for medical assistance, as defined in section 1903(u)(1)(D)(i) of the Act, is calculated for both the Medicaid program and CHIP during the audit period using the lower limit of the 90 percent confidence interval, if applicable.

(d) The Federal share of payments determined to be inappropriately made for erroneous excess payments for medical assistance during the audit period are subject to potential disallowances if one or both of the calculated eligibility error rates described in § 455.706(c) exceed the allowable 3 percent threshold under section 1903(u) of the Act, unless the State meets the good faith waiver requirements defined in § 455.804.

§ 455.708 Protection of applicant and beneficiary information and due process rights.

The State Medicaid agency performing activities for the eligibility audits specified in this

subpart must do so in a manner that is consistent with all of the following:

(a) Part 431, subpart F of this chapter concerning the safeguarding of beneficiary and applicant information.

(b) 42 CFR 435.930(b), 435.917, 435.918;.part 431, subpart E; and 457.1110 of this chapter concerning the continuation of Medicaid of coverage for eligible individuals until the State has made a final determination of ineligibility and provided advance notice and fair hearing rights.

§ 455.710 Access to records.

The State, upon written request, must submit to CMS and its Federal contractors, all necessary records, including complete eligibility case documentation for sampled cases and all other available documents pertaining to eligibility determinations in effect during the audit period.

§ 455.712 Corrective action plans.

(a) The State is required to submit a CAP for approval in accordance with § 455.602, if applicable.

(b) After obtaining approval for a CAP, the State is required to make sufficient progress towards implementing the CAP within the established milestone timeframes as specified in § 455.602.

Subpart I - Medicaid and CHIP Beneficiary Eligibility-Related Disallowances

Sec.

455.800 Purpose.

455.802 Disallowance of Federal financial participation for eligibility errors.

455.804 Good faith waivers and **n**otice to States.

455.806 Appeals.

Subpart I – Medicaid and CHIP Beneficiary Eligibility-Related Disallowances

§ 455.800 Purpose.

This section establishes rules and procedures for disallowing Federal financial participation (FFP) in erroneous medical and child health assistance payments due to eligibility improper payment errors, as identified through the Medicaid and CHIP beneficiary eligibility audits subject to disallowance established under Subpart H of this part.

§ 455.802 Disallowance of Federal financial participation for eligibility errors.

(a) After the State's eligibility error rates for Medicaid and CHIP have been calculated in accordance with § 455.706(c) during a beneficiary eligibility audit, if applicable, CMS computes the amount of the disallowances and adjusts the FFP payable to the State in accordance with the procedures in § 430.42.

(b) CMS computes the amount to be disallowed for Medicaid and CHIP separately as follows:

(1) Subtract the 3 percent allowable threshold from the lower limit of the State's Medicaid or CHIP eligibility error rate percentage.

(2) If the difference is greater than zero, the corresponding Federal share of medical assistance or child health assistance funds for the period are multiplied by that percentage. This product is the amount of the disallowance of FFP that will be adjusted in a future State expenditure report absent a good faith waiver in accordance with § 455.804.

§ 455.804 Good faith waivers and notice to States.

(a) If CMS is satisfied that the State did not meet the 3 percent allowable threshold despite a good faith effort, CMS may reduce the funds being disallowed, in whole or in part, based on the extent to which the State demonstrates compliance with the criteria in paragraph (b) of this section and the evidence submitted under paragraph (c) of this section.

(b) CMS may find that a State did not meet the 3 percent allowable threshold despite a good faith effort if all of the following requirements are met:

(1) The State implemented the eligibility-related elements of its most recent CMS-approved PERM CAP in accordance with § 431.992.

(2) Where applicable, the State submitted a CAP under § 455.712 in response to previous Medicaid and CHIP beneficiary eligibility audit findings, obtained CMS approval of that CAP, and is making sufficient progress implementing the approved CAP within its established milestone timeframes at the time of the good faith waiver determination.

(3)(i) The State has taken additional reasonable actions to prevent, identify, or mitigate eligibility errors it believed were necessary to meet the 3 percent threshold.

(ii) In determining whether a State took reasonable actions, CMS considers factors including, but not limited to, the following:

(A) Whether the State maintained reasonable pre-existing eligibility controls.

(B) Whether the same eligibility errors had been identified in previous audits or reviews.

(C) The timeliness and substance of the State's response after error identification.

(Dv) Immediate corrective actions already taken.

(Ev) Cooperation and transparency during CMS audits and reviews.

(c)(1) The State must submit evidence demonstrating its actions under paragraph (b) of this section within 30 calendar days of CMS' issuance of the final Medicaid and CHIP beneficiary eligibility audit report and notification of the associated disallowance amount, unless granted an extension by CMS.

(2) Evidence submission may include all of the following:

(i) Policy manuals.

(ii) Staff training records;

(iii) Documentation of eligibility and enrollment system enhancements.

(iv) Self-audit reports.

(v) Detailed CAPs with proof of implementation and effectiveness.

(d) Notwithstanding paragraphs (a) through (c) of this section, CMS may determine that a State is ineligible for a good faith waiver or is eligible for only a partial waiver where the information and evidence available to CMS demonstrates systemic or persistent program

integrity failures inconsistent with a good faith effort during the audit period.

(e) Circumstances that may warrant a determination under paragraph (d) of this section include, but are not limited to any of the following:

(1) Repeated beneficiary eligibility audit or PERM findings involving the same or substantially similar errors.

(2) Failure to address or implement prior CMS audit recommendations related to eligibility determination errors.

(3) Known system defects, operational deficiencies, or policy weaknesses affecting eligibility determinations that remained unaddressed by the State during the audit period.

(4) Patterns of noncompliance identified across multiple Federal oversight activities.

(f) Each State that has an eligibility improper payment rate above the allowable threshold is notified by CMS in writing of the good faith waiver determination, including whether CMS granted a full waiver, a partial waiver, or no waiver, and, where applicable, the amount of the disallowance issued under § 455.802. This written notification would also include the information specified in §430.42(a), as appropriate, including notice of the State's right to request reconsideration of the disallowance.

§ 455.806 Appeals.

If a State disagrees with the determinations set forth in the written notice described in § 455.804(f), the State may request reconsideration or appeal within 60 calendar days of receipt of the notice. All processes regarding the notice of disallowance, reconsideration, retention of funds, and appeals will be governed by the procedures set forth in § 430.42 of this chapter.

Subpart J – Reporting and Returning of Overpayments in Medicaid Fee-for-Service

§ 455.900 Basis and scope.

This subpart sets forth the policies and procedures for reporting and returning self-identified overpayments to the Medicaid Fee-For-Service program as required by section 1128J(d) of the Act.

§ 455.902 Definitions.

For purposes of this subpart only –

Overpayment means any funds that a person received or retained under title XIX of the Act to which the person is not entitled under such title after applicable reconciliation.

Person means a provider of services or supplier who participates under a State plan (or waiver of such plan) established under title XIX of the Act.

§ 455.904 Requirements for reporting and returning of overpayments.

(a) *General*.

(1) A person that has received an overpayment must report and return the overpayment to the State, including a written reason for the overpayment, in the form and manner specified by the State in accordance with paragraph (c) (1) of this section.

(2) A person has identified an overpayment when the person knowingly receives or retains an overpayment. The term "knowingly" has the meaning set forth in 31 U.S.C. 3729(b)(1).

(b) *Deadline for reporting and returning overpayments*. A person who has received an overpayment must report and return the overpayment to the State by the later of either of the following:

(1) The date which is 60 days after the date on which the overpayment was identified.

(2) The date any corresponding cost report is due, if applicable.

(c) *State responsibilities*. A State must do all of the following:

(1) Establish a mechanism for a person to report and return to the State when an overpayment is identified, in accordance with paragraph (b) of this section.

(2) Return the Federal share of overpayments to CMS consistent with the requirements in 42 CFR 433.312.

(3) Maintain a record of all reported or received overpayments and make such records available to CMS upon request.

(d) *Reporting*. A person must use the mechanism established by the State in paragraph (c)(1) of this section to report and return an identified overpayment to the State. If the person calculates the overpayment amount using a statistical sampling methodology, the person must describe the statistically valid sampling and extrapolation methodology in the report.

(e) *Enforcement*. Any overpayment retained by a person after the deadline for reporting and returning the overpayment specified in paragraph (b) of this section is an obligation for purposes of the False Claims Act, 31 U.S.C. 3729(b)(3).

(f) *Lookback period*. An overpayment must be reported and returned in accordance with this section if a person identifies the overpayment, as defined in paragraph (a)(2) of this section, within 6 years of the date the overpayment was received.

PART 457 – ALLOTMENTS AND GRANTS TO STATES

54. The authority citation for part 457 continues to read as follows:

Authority: 42 U.S.C. 1302.

55. Section 457.628 is amended by revising paragraph (a) to read as follows:

§ 457.628 Other applicable Federal regulations.

* * * * *

(a) HHS regulations in the following sections:

(1) Sections 431.950 through 431.1002 of this chapter (related to the PERM program).

(2) Sections 433.312 through 433.322 of this chapter (related to Overpayments).

(3) Section 433.38 of this chapter (Interest charge on disallowed claims of FFP).

(4) Sections 430.40 through 430.42 of this chapter (Deferral of claims for FFP and Disallowance of claims for FFP).

(5) Section 430.48 of this chapter (Repayment of Federal funds by installments).

(6) Sections 433.50 through 433.74 of this chapter (sources of non-Federal share and Health Care-Related Taxes and Provider Related Donations).

(7) Section 447.207 of this chapter (Retention of Payments).

(8) Sections 455.700 through 455.806 (related to the Beneficiary eligibility audit program) of this chapter

apply to States CHIP programs in the same manner as they apply to States Medicaid programs.

* * * * *

56. Section 457.935 is amended by adding paragraph (b)(8) to read as follows:

§ 457.935 Sanctions and related penalties.

(b) * * *

(8) Section 455.23 of this chapter.

* * * * *

PART 498 – APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/IID AND CERTAIN NFs IN THE MEDICAID PROGRAM

57. The authority citation for part 498 continues to read as follows:

Authority:42 U.S.C. 1302, 1320a-7j, and 1395hh.

Source:52 FR 22446, June 12, 1987, unless otherwise noted.

Section 498.3 is amended by---

a. Redesignating paragraph (b)(20) as new paragraph (b)(20)(i).

b. Removing the phrase "§ 422.2 or" from new paragraph (b)(20)(i).

c. Adding new paragraph (b)(20)(ii).

The addition reads as follows:

§ 498.3 Scope and applicability.

* * * *

(b) * * *

(20) * * *

(ii) Before January 1, 2030, an individual or entity is to be included on the preclusion list

as defined in § 422.2 of this chapter.

* * * * *

58. Section 498.5 is amended by revising paragraph (n)(1)(i) to read as follows:

§ 498.5 Appeal rights.

* * * * *

(n) * * *

(1) * * *

(i)(A) Any individual or entity that is dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list (as defined in § 423.100 of this chapter) may request a reconsideration in accordance with § 498.22(a). (B) Before January 1, 2030, any individual or entity that is dissatisfied with an initial determination or revised initial determination that they are to be included on the preclusion list (as defined in § 422.2 of this chapter) may request a reconsideration in accordance with § 498.22(a).

* * * * *

Title 45 – Public Welfare

PART 155 – EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

59. The authority citation for part 155 continues to read as follows:

Authority: 42 U.S.C. 18021-18024, 18031-18033, 18041-18042, 18051, 18054, 18071, and 18081-18083.

60. Section 155.20 is amended by adding the definitions of "Credible allegation of abusive conduct" and "Convicted" in alphabetical order to read as follows:

Credible allegation of abusive conduct. A credible allegation of abusive conduct is an allegation from any source, including but not limited to the following:

(1) Consumer, Marketplace call center, or agent, broker, or web-broker complaints verified by further evidence;

(2) Data or information identified during investigation; or

(3) Patterns identified through data analysis.

Allegations are considered to be credible when they have indicia of reliability.

Convicted means that—

(1) A judgment of conviction has been entered against an individual or entity by a Federal, State or local court, regardless of whether:

(i) There is a post-trial motion or an appeal pending;', or(ii) The judgment of conviction or other record relating to the criminal conduct has been expunged or otherwise removed;

(2) A Federal or State court has accepted a plea of guilty or *nolo contendere* or an Alford plea by an individual or entity; or

(3) An individual or entity has entered into participation in a first offender, deferred adjudication or other program or arrangement where judgment of conviction has been withheld.

61. Section 155.220 is amended by:

a. Revising paragraph (g)(1), adding paragraph (g)(1)(i), revising paragraphs (g)(3)(i) and (g)(3)(ii), adding paragraphs (g)(3)(iii) and (g)(3)(iv), and revising paragraphs (g)(4) and (g)(5);

b. Revising paragraph (h)(1) and adding new paragraphs (h)(1)(i), (h)(1)(ii), and (h)(1)(iii);

c. Revising paragraphs (j)(2)(i) and (j)(2)(ii) and adding new paragraph (j)(2)(ix); and

d. Revising paragraph (k).

The revisions and additions read as follows:

§ 155.220 Ability of States to permit agents and brokers and web-brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(g) * * *

(1) HHS may terminate for cause an agent's, broker's, or web-broker's agreements with the Federally-facilitated Exchanges and State-based Exchanges on the Federal Platform (SBE-FPs) (required under paragraph (d) of this section and § 155.260(b)), if HHS determines that the agent, broker, or web-broker is noncompliant as described in paragraph (g)(2) of this section. In that case, HHS may also impose one or more of the penalties identified in paragraph (k)(1) of this section.

(i) Except for terminations made pursuant to paragraphs (g)(3)(ii) through (g)(3)(iv) of this section, when HHS makes a noncompliance determination under paragraph (g)(1), HHS will consider the factors identified in § 155.285(b)(1) and (2) to the extent relevant to the facts and circumstances of each case, as well as any additional relevant factors supported by the evidence when it: (A) Decides whether to terminate an agent, broker, or web-broker's agreements (described in paragraph (d) of this section and § 155.260(b)) for cause; or (B) Selects among the penalties identified in paragraph (k)(1) of this section, including the length of the penalty imposed under paragraph (k)(1)(i) of this section.

(2) * * *

(3) * * *

(i) Except as provided in paragraphs (g)(3)(ii) through (g)(3)(iv) of this section, HHS will first notify the agent, broker, or web-broker of a noncompliance determination made under paragraph (g)(1) of this section. The agent, broker, or web-broker will have 30 calendar days after the date of the notice to submit information to HHS refuting the noncompliance determination. After reviewing any refutation evidence submitted, HHS may terminate the agent, broker, or web-broker’s agreements required under paragraph (d) of this section and § 155.260(b) for cause if HHS determines, based on the evidence available to HHS, that a preponderance of the evidence establishes that noncompliance occurred. The failure to submit evidence to refute does not preclude HHS from making such a determination based on the evidence otherwise available to HHS.

(ii) If an agent or broker fails to maintain the appropriate license under State law to act as an agent, broker, or insurance producer in every State where the agent or broker actively assists consumers with applying for advance payments of the premium tax credit or cost-sharing reductions, or with enrolling in QHPs through the Federally-facilitated Exchanges or SBE-FPs, HHS may immediately terminate the agreements (required under paragraph (d) of this section and § 155.260(b)) for cause upon notice to the agent or broker, without first providing the agent or broker an opportunity to refute the determination under paragraph (g)(3)(i) of this section.

(iii) HHS may deny registration to, or terminate the agreements for cause with any agent, broker, or web-broker who--

(A) Is currently terminated, suspended, or revoked (or otherwise barred or excluded) from participation in any Federal program; or

(B) Has a license that is currently revoked or suspended for conduct that may cause harm to consumers or program integrity in a State other than the State in which the agent, broker, or web-broker is enrolling consumers. This applies regardless of whether any appeal(s) of the exclusion, termination, suspension, or revocation is pending. HHS may take action under this paragraph (g)(3)(iii) of this section upon notice to the agent, broker, or web-broker, without first providing an opportunity to refute the determination under paragraph (g)(3)(i) of this section. If the agent, broker, or web-broker subsequently demonstrates to HHS that the exclusion, termination, suspension, or revocation has been vacated or reversed on appeal and no other grounds for denial of registration exist, HHS will permit the agent, broker, or web-broker to register with the Exchange.

(iv) HHS may deny registration to, or immediately terminate the agreements for cause with, any agent, broker, or web-broker who was convicted of a Federal or State misdemeanor or felony offense that HHS determines is detrimental to the best interests of the FFEs, SBE-FPs, or their consumers, regardless of whether the conviction has been appealed. HHS may take this action upon notice to the agent, broker, or web-broker, without first providing an opportunity to

refute the determination under paragraph (g)(3)(i) of this section. If the agent, broker, or web-broker subsequently demonstrates to HHS that the conviction has been vacated or reversed on appeal and no other grounds for denial of registration exist, HHS will permit the agent, broker, or web-broker to register with the Exchange.

(A) These misdemeanor or felony offenses include, but are not limited in scope or severity to—

(*1*) Misdemeanor and felony crimes against persons, such as murder, rape, assault, and other similar crimes for which the individual was convicted, including guilty pleas and adjudicated pretrial diversions.

(*2*) Financial crimes, such as extortion, embezzlement, income tax evasion, insurance fraud, identity theft, forgery, bribery, falsification or destruction of records, receiving stolen property, making false statements or claims, violation of consumer protection laws, and other similar crimes for which the individual was convicted.

(*3*) Any misdemeanor or felony that places the Federally-facilitated Exchanges, SBE-FPsor their consumers at immediate risk, such as a conviction of criminal neglect or misconduct.

(*4*) Any misdemeanor or felony that would result in mandatory exclusion under section 1128(a) of the Act.

(4) If HHS terminates the agreements (described in paragraph (d) of this section and § 155.260(b)), the agent, broker, or web-broker will no longer be registered with the Federally-facilitated Exchanges or SBE-FPs, or be permitted to assist with or facilitate enrollment of a qualified individual, qualified employer, or qualified employee in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchanges or SBE-FPs, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs.

(i) The agent, broker, or web-broker's agreements with the Exchange under § 155.260(b)(2) will also be terminated through the process set forth in that agreement.

(ii) The termination is effective on the date specified in the notice HHS sends to the agent, broker, or web-broker advising the agent, broker, or web-broker of the termination of the agreement.

(iii)The agent, broker, or web-broker must continue to protect any personally identifiable information accessed during the term of any agreement with a Federally-facilitated Exchanges and SBE-FPs.

(5) * * *

(i) Abusive conduct is any conduct that is likely to cause or has caused harm to the Federally-facilitated Exchanges, SBE-FPs, or their consumers. Abusive conduct includes, but is not limited to, any of the following:

(A) A violation of the standards of conduct at 45 CFR 155.220(j)(2).

(B) Providing the Federally-facilitated Exchanges or SBE-FPs with inaccurate application information related to the consumer's eligibility for Medicaid, CHIP, a QHP offered through the Exchange, advance premium tax credit, or cost-sharing reductions.

(C) A violation of any term or condition of the agreements with the Federally-facilitated Exchanges and SBE-FPs (required under paragraph (d) of this section and § 155.260(b)) that relates to the agent, broker, or web-broker's conduct toward consumers.

(D) Any other misleading or coercive conduct identified by HHS.

(ii) If HHS finds that an allegation of abusive conduct against an agent, broker, or web-broker is credible, as defined in 45 CFR 155.20, HHS may suspend the agent, broker, or web-broker's agreements required under paragraph (d) of this section and under § 155.260(b) for 90 calendar days.

(A) Suspension will be effective on the date of the notice that HHS sends to the agent, broker, or web-broker advising of the suspension of the agreements.

(B) The agent, broker, or web-broker may submit evidence, in a form and manner specified by HHS, to rebut the allegation that led to the suspension. The agent, broker, or web-

broker must submit any such evidence within 30 calendar days of the suspension. HHS will review any evidence submitted and make a determination whether to lift the suspension within the 90-day period.

(iii) HHS may terminate for cause the agent, broker, or web-broker's agreements required under paragraph (d) of this section and § 155.260(b) if, after reviewing any rebuttal evidence submitted, HHS determines by a preponderance of the evidence that abusive conduct occurred.

(iv) During the suspension period under paragraph (g)(5)(ii) of this section and following termination of the agreements under paragraph (g)(5)(iii) of this section, the agent, broker, or web-broker will not be registered with the Federally-facilitated Exchanges and SBE-FPs, or be permitted to assist with or facilitate enrollment of qualified individuals, qualified employers, or qualified employees in coverage in a manner that constitutes enrollment through a Federally-facilitated Exchange, or be permitted to assist individuals in applying for advance payments of the premium tax credit and cost-sharing reductions for QHPs. The agent, broker, or web-broker must continue to protect any personally identifiable information accessed during the term of either of these agreements with the Federally-facilitated Exchanges and SBE-FPs.

(6) The State department of insurance, or equivalent State licensing authority for agents or brokers, will be notified by HHS in cases of suspension, termination, or penalty imposed, under paragraphs (g) or (k)(1) of this section.

* * * * *

(h) * * *

(1) *Request for reconsideration.* An agent, broker, or web-broker may request reconsideration, in the manner and form established by HHS, of the following:

(i) HHS' decision to terminate the agent, broker, or web-broker's agreement with the Federally-facilitated Exchange under paragraph (g) of this section;

(ii) HHS' decision to deny registration with the Federally-facilitated Exchanges and SBE-FPs under paragraph (g)(3)(iii) or (iv) of this section; or

(iii) HHS' decision to impose a penalty under paragraph (k)(1)(i) of this section.

* * * * *

(j) * * *

(2) * * *

(i) Provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges and SBE-FPs, and insurance affordability programs. Refrain from marketing or conduct that is misleading, coercive, or discriminates based on race, color, national origin, disability, age, or sex. Misleading or coercive conduct may include, but are not limited to, either of the following--

(A) Having a website that HHS determines could mislead a consumer into believing the consumer is visiting *HealthCare.gov,* an official Marketplace, ACA or Exchange enrollment website, certified Exchange enrollment partner website, or any other official website of the Federal or a State government**,** and

(B) Falsely claiming to represent the Federally-facilitated Exchange or State-based Exchanges on the Federal platform, or falsely suggesting that coverage from the Federally-facilitated Exchange or State-based Exchanges on the Federal platform is free.

(ii) * * *

* * * * *

(E) * * *

(1) An agent, broker, or web-broker may not use or project, or ask a consumer to use or project, on the Exchange eligibility application, the following:

(*i*) An annual income that is not based on any actual or reasonably expected source of income.

(*ii*) Income the consumer is unlikely to earn.

(*iii*) Income that omits one or more tax household members.

(*iv*) Income based on inappropriate modified adjusted gross income calculations, such as projecting income based on income after income tax withholding.

(*v*) A predetermined income amount that the consumer is coached, targeted, or steered towards by the agent, broker, or web-broker.

(F) Submitting application and enrollment data only for consumers who are not deceased at the time of enrollment.

(G) Accurately entering information provided and confirmed by the consumer pertaining to any existing minimum essential coverage as defined by 45 CFR part 156 Subpart G, that the consumer is eligible for or enrolled in.

(H) Accurately entering information provided and confirmed by the consumer pertaining to all tax household members. Agents, brokers, and web-brokers must ask consumers about their household composition to the same extent consumers are asked about household composition on the Exchange eligibility application and accurately report each consumer response. (I) Accurately entering information provided and confirmed by the consumer regarding residence address pursuant to 45 CFR 155.305(a)(3).

(J) Accurately entering information provided and confirmed by the consumer regarding household contact information including names, phone number and mailing address, and if the consumer chooses to provide them, accurate email address and mobile phone number for text messages. Consumer contact information must only be the consumer's personal contact information and cannot be contact information accessible or controlled by an agent, broker, web-broker or any other non-consumer persons or entities.

(K) Using customer service channels that HHS determines do not mislead a consumer into believing the consumer is providing information to or enrolling through an official Exchange, Marketplace, or ACA customer service pathway or representative, or through certified Exchange enrollment partners.

* * * * *

(ix) Implement and maintain reasonable administrative, technical, and contractual safeguards designed to ensure that access and attempted access to the Federally-facilitated Exchanges and SBE-FPs, systems that support the Federally-facilitated Exchanges and SBE-FPs, and personally identifiable information obtained through the Federally-facilitated Exchanges and SBE-FPs by the individual or entity described in paragraph (j)(1) of this section and all employees, contractors, subcontractors, and other downstream entities acting on their behalf, occur only from locations within the United States, its territories, embassies, or military installations.

(A) Such reasonable safeguards must include safeguards to ensure that VPNs or other similar technologies do not route Exchange system traffic through a server, network, or other point located outside the United States, its territories, embassies, or military installations, regardless of whether the agent, broker, or web-broker is physically located inside the United States, its territories, embassies, or military installations at the time of access, and regardless of whether the technology causes the access to appear to originate from a location inside the United States, its territories, embassies, or military installations.

(B) An agent, broker, or web-broker will not be considered to have failed to satisfy the requirements of paragraph (j)(2)(ix) of this section due to unauthorized activity resulting from compromised credentials or inadvertent network activity that the agent, broker, or web-broker could not reasonably have known about or prevented through reasonable safeguards.

* * * * *

(4) Except for suspensions or terminations under paragraph (g)(5) of this section, if an agent, broker, or web-broker fails to provide correct information, the agent, broker, or web-broker will nonetheless be deemed in compliance with paragraphs (j)(2)(i) and (ii) of this section if HHS determines that there was a reasonable cause for the failure to provide correct information and that the agent, broker, or web-broker acted in good faith. For suspensions or terminations under paragraph (g)(5) of this section, conduct resulting solely from inadvertent

error, notwithstanding reasonable compliance, measures does not constitute abusive conduct.

* * * * *

(k) * * *

(1) If HHS determines that an agent, broker, or web-broker is noncompliant as described in paragraph (g)(2) of this section, or has engaged in abusive conduct as described in paragraph (g)(5) of this section, in addition to or as an alternative to any other available remedies, that agent, broker, or web-broker—

(i) * * *

(ii) * * *

(2) HHS will notify the agent, broker, or web-broker of the imposition of penalties under paragraph (k)(1)(i) of this section as part of the termination notice issued under paragraph (g) of this section. The proposed imposition of penalties under paragraph (k)(1)(ii) of this section will follow the process outlined under § 155.285.

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Robert F. Kennedy, Jr.,

Secretary,

Department of Health and Human Services.

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