DEPARTM

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-367a – e, CMS-10330, CMS-10780, CMS-10524 and CMS-906]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

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

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain . Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed

collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at Web Site address at: https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate Program Labeler Reporting Format; *Use*: Labelers transmit drug product and pricing data to CMS within 30 days after the end of each calendar month and quarter. CMS calculates the unit rebate amount (URA) and the unit rebate offset amount (UROA) for each new drug application (NDC) and distributes to all State Medicaid agencies. States use the URA to invoice the labeler for rebates and the UROA to report onto CMS-64. The monthly data is used to calculate Federal Upper Limit (FUL) prices for applicable drugs and for states that opt to use this data to establish their pharmacy reimbursement methodology. In this November 2021 iteration, CMS-367d (Manufacturer Contact Form) is being revised to include a signature/date line for the submitter to confirm that

the information provide is accurate, and we have additionally updated the entire 367d to a fillable format, per multiple labeler requests. CMS-367e (Quarterly VBP-MBP Data) is a new form that is intended for manufacturers to use (as needed) on a quarterly basis, to transmit pricing data (best prices associated with value-based purchasing (VBP) arrangements) for each of their covered outpatient drugs (CODs) to CMS either via direct file upload to the MDP System or manual on-line entry. The CMS-367e form is optional. We are not proposing any changes to the CMS-367a (Quarterly Pricing), CMS-367b (Monthly Pricing), or CMS-367c (Product Data) forms. *Form Number*: CMS-367a, b, c, d, and e (OMB control number: 0938-0578); *Frequency*: Monthly, quarterly, and on occasion; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 780; *Total Annual Responses*: 15,020; *Total Annual Hours:* 564,394. (For policy questions regarding this collection contact Andrea Wellington at 410-786-3490.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Notice of Rescission of Coverage and Disclosure Requirements for Patient Protection under the Affordable Care Act; *Use:* Sections 2712 and 2719A of the Public Health Service Act (PHS Act), as added by the Affordable Care Act, contain rescission notice, and patient protection disclosure requirements that are subject to the Paperwork Reduction Act of 1995. The No Surprises Act, enacted as part of the Consolidated Appropriations Act, 2021, amended section 2719A of the PHS Act to sunset when the new emergency services protections under the No Surprises Act take effect. The provisions of section 2719A of the PHS Act will no longer apply with respect to plan years beginning on or after January 1, 2022. The No Surprises Act re-codified the patient protections related to choice of health care professional under section 2719A of the PHS Act in newly added section 9822 of the Internal Revenue Code, section 722 of the Employee Retirement Income Security Act, and section 2799A-7 of the PHS Act and extended the applicability of these provisions to grandfathered health plans for plan years beginning on or after January 1, 2022. The rescission

notice will be used by health plans to provide advance notice to certain individuals that their coverage may be rescinded as a result of fraud or intentional misrepresentation of material fact. The patient protection notification will be used by health plans to inform certain individuals of their right to choose a primary care provider or pediatrician and to use obstetrical/gynecological services without prior authorization. The related provisions are finalized in the 2015 final regulations titled "Final Rules under the Affordable Care Act for Grandfathered Plans, Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, Dependent Coverage, Appeals, and Patient Protections" (80 FR 72192, November 18, 2015) and 2021 interim final regulations titled "Requirements Related to Surprise Billing; Part I" (86 FR 36872, July 13, 2021). The 2015 final regulations also require that, if State law prohibits balance billing, or a plan or issuer is contractually responsible for any amounts balanced billed by an out-of-network emergency services provider, a plan or issuer must provide a participant, beneficiary or enrollee adequate and prominent notice of their lack of financial responsibility with respect to amounts balanced billed in order to prevent inadvertent payment by the individual. Plans and issuers will not be required to provide this notice for plan years beginning on or after January 1, 2022. *Form Number*: CMS-10330 (OMB control number: 0938-1094); *Frequency*: On Occasion; *Affected Public*: State, Local, or Tribal Governments, Private Sector; *Number of Respondents:* 2,277; *Total Annual Responses:* 15,752; *Total Annual Hours:* 814. (For policy questions regarding this collection, contact Usree Bandyopadhyay at 410-786-6650.)

3. *Type of Information Collection Request*: Extension of a currently approved collection; *Title of Information Collection*: Requirements Related to Surprise Billing: Qualifying Payment Amount, Notice and Consent, Disclosure on Patient Protections Against Balance Billing, and State Law Opt-in; *Use*: On December 27, 2020, the Consolidated Appropriations Act, 2021 (Pub. L. 116-260), which included the No Surprises Act, was signed into law. The No Surprises Act provides federal protections against surprise billing and limits out-of-network cost sharing under many of the circumstances in which surprise medical bills arise most frequently.

The 2021 interim final regulations "Requirements Related to Surprise Billing; Part I" (86 FR 36872, 2021 interim final regulations) issued by the Departments of Health and Human Services, the Department of Labor, the Department of Treasury, and the Office of Personnel Management, implement provisions of the No Surprises Act that apply to group health plans, health insurance issuers offering group or individual health insurance coverage, and carriers in the Federal Employees Health Benefits (FEHB) Program that provide protections against balance billing and out-of-network cost sharing with respect to emergency services, non-emergency services furnished by nonparticipating providers at certain participating health care facilities, and air ambulance services furnished by nonparticipating providers of air ambulance services. The 2021 interim final regulations prohibit nonparticipating providers, emergency facilities, and providers of air ambulance services from balance billing participants, beneficiaries, and enrollees in certain situations unless they satisfy certain notice and consent requirements. The No Surprises Act and the 2021 interim final regulations require group health plans and issuers of health insurance coverage to provide information about qualifying payment amounts to nonparticipating providers and facilities and to provide disclosures on patient protections against balance billing to participants, beneficiaries and enrollees. Self-insured plans opting in to a specified state law are required to provide a disclosure to participants. Certain nonparticipating providers and nonparticipating emergency facilities may provide participants, beneficiaries, and enrollees with notice and obtain their consent to waive balance billing protections, provided certain requirements are met. In addition, certain providers and facilities are required to provide disclosures on patient protections against balance billing to participants, beneficiaries and enrollees. *Form Number*: CMS-10780 (OMB control number: 0938-1401); *Frequency*: On Occasion; *Affected Public*: Individuals, State, Local, or Tribal Governments, Private Sector; *Number of Respondents:* 2,494,683; *Total Annual Responses:* 58,696,352; *Total Annual Hours:* 4,933,110. (For policy questions regarding this collection, contact Usree Bandyopadhyay at 410-786-6650.)

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetic, Orthotics, and Supplies (DMEPOS); *Use:* Section 1834(a)(15) of the Social Security Act (the Act) authorizes the Secretary to develop and periodically update a list of DMEPOS that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization and to develop a prior authorization process for these items. Pursuant to this authority, CMS published final rules CMS-6050-F and CMS-1713-F.

The information required under this collection is used to determine proper payment and coverage for DMEPOS items. The information requested includes all documents and information that demonstrate the DMEPOS item requested is reasonable and necessary for the beneficiary and meets applicable Medicare requirements. The documentation will be reviewed by trained registered nurses, therapists, or physician reviewers to determine if item(s) or service requested meets all applicable Medicare coverage, coding and payment rules. *Form Number*: CMS-10524 (OMB control number: 0938-1293); *Frequency*: Occasionally; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 273,305; *Total Annual Responses:* 273,305; *Total Annual Hours:* 136,652. (For policy questions regarding this collection contact Stephanie Collins at (410) 786-0959.)

5. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Fiscal Soundness Reporting Requirements (FSRR); *Use:* Title 18 Section 1857(d)(4)(A)(i) requires that contracting organizations such as Medicare Health Plans (including Medicare Advantage (MA) organizations, Medicare-Medicaid Capitated Financial Alignment Demonstrations (MMPs)) and 1876 Cost Plans), Prescription Drug Plan sponsors (PDPs), and Programs of All-Inclusive Care for the Elderly (PACE) organizations report financial information demonstrating the organization has a fiscally sound operation. The FSRR is designed to capture financial data of these contracting entities. The Division of Finance

and Benefits (DFB) within the Medicare Advantage Contract Administration Group (MCAG) of CMS is assigned the responsibility of reviewing ongoing financial performance of the contracting entities.

All contracting organizations must submit audited annual financial statements one time per year. In addition to the audited annual submission, Health Plans with a negative net worth and/or a net loss and the amount of that loss is greater than one-half of the organization's total net worth submit quarterly financial statements for fiscal soundness monitoring. Part D organizations are required to submit three (3) quarterly financial statements. Lastly, PACE organizations are required to file four (4) quarterly financial statements for the first three (3) years in the program. After the first three (3) years, PACE organizations with a negative net worth and/or a net loss and the amount of that loss is greater than one-half of the organization's total net worth must submit quarterly financial statements for fiscal soundness monitoring. *Form Number*: CMS-906 (OMB control number: 0938-0496); *Frequency*: Quarterly and Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 936; *Total Annual Responses:* 1,958; *Total Annual Hours:* 652. (For policy questions regarding this collection contact Christa M. Zalewski at (410) 786-1971.)

Dated: March 1, 2022.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

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