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CMS-6037-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 401 and 405

[CMS-6037-P]

RIN 0938-AQ58

Medicare Program; Reporting and Returning of Overpayments

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would require providers and suppliers receiving funds under the Medicare program to report and return overpayments by the later of the date which is 60 days after the date on which the overpayment was identified; or any corresponding cost report is due, if applicable.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on [OFR: Insert date 60 days after date of publication in the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-6037-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. 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-6037-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-6037-P

Mail Stop C4-26-05

7500 Security Boulevard

Baltimore, MD 21244-1850

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC--

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD--

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-1066 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

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

FOR FURTHER INFORMATION CONTACT: Tiana Korley, (410) 786-9702.

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 Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

The Medicare program (title XVIII of the Social Security Act (the Act)) is the primary payer of health care for approximately 47 million enrolled beneficiaries. Providers and suppliers furnishing Medicare items and services must comply with the Medicare requirements set forth in the Act and in our regulations. The requirements are meant to ensure compliance with applicable statutes, promote the furnishing of high quality care, and to protect the Medicare Trust Funds against fraud and improper

payments. As Medicare spending has grown, we have increased our efforts to reduce fraud, waste, and abuse in the Medicare program.

As part of these efforts we have twice proposed – but did not finalize – rules that would have amended our regulations related to Medicare overpayments. (See the March 25, 1998 (63 FR 14506) and January 25, 2002 (67 FR 3662) proposed rules.)

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111-148) was enacted. The Health Care Education Reconciliation Act of 2010 (Pub. L. 111-152) then amended certain provisions of Pub. L. 111-148. These public laws are collectively known as the Affordable Care Act. The Affordable Care Act makes a number of changes to the Medicare program that enhance our efforts to recover overpayments and combat fraud, waste and abuse in the Medicare program.

Section 6402(a) of the Affordable Care Act established a new section 1128J(d) of the Act entitled "Reporting and Returning of Overpayments." 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, at the correct address, and to notify the Secretary, State, intermediary, carrier or contractor to whom the overpayment was returned in writing of the reason for the overpayment. Section 1128J(d)(2) of the Act requires that an overpayment be reported and returned by the later of-- (1) the date which is 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 (as defined in 31 U.S.C. 3729(b)(3)) for purposes of 31 U.S.C. 3729.

Section 1128J(d)(4)(A) defines "knowing" and "knowingly" as those terms are defined in 31 U.S.C. 3729(b); the terms "knowing" and "knowingly" "mean that a person with respect to information -- (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." There need not be "proof of specific intent to defraud." Section 1128J(d)(4)(B) of the Act defines the term "overpayment" as any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title. Finally, section 1128J(d)(4)(C) of the Act defines the term "person" as a provider of services, supplier, Medicaid managed care organization (MCO) (as defined in section 1903(m)(1)(A) of the Act), Medicare Advantage organization (MAO) (as defined in section 1859(a)(1) of the Act) or PDP sponsor (PDP) (as defined in section 1860D-41(a)(13) of the Act) but the definition does not include a beneficiary.

II. Provisions of the Proposed Regulation

To implement section 6402(a) of the Affordable Care Act, we propose establishing a new subpart D in Part 401 of our regulations. In this section, we outline the content of the proposed provisions of this new subpart D.

A. Scope of Subpart (Proposed § 401.301)

In proposed §401.301, we state that subpart D sets forth the policies and procedures for reporting and returning overpayments to the Medicare program for providers and suppliers of services under Parts A and B of title XVIII. At this time, we are proposing to implement the requirements set forth in section 1128J(d) of the Act only as they relate to Medicare Part A and Part B providers and suppliers. Other stakeholders,

including, without limitation, MAOs, PDPs, and Medicaid MCOs will be addressed at a later date.

Notwithstanding the foregoing, we remind all stakeholders that even without a final regulation they are subject to the statutory requirements found in section 1128J(d) of the Act and could face potential False Claims Act liability, Civil Monetary Penalties Law liability, and exclusion from Federal health care programs for failure to report and return an overpayment. Additionally, providers and suppliers continue to be obliged to comply with our current procedures when we, or our contractors, determine an overpayment and issue a demand letter.

B. Definitions (Proposed §401.303)

For purposes of this subpart only, we propose the following definitions:

1. Overpayment

Section 1128J(d) of the Act provides that an overpayment means "...any funds that a person receives or retains under title XVIII...to which the person, after applicable reconciliation, is not entitled under such title." In §401.303, we propose to include this same definition in our proposed rule. Examples of overpayments under this proposed definition could include all of the following:

- Medicare payments for noncovered services.
- Medicare payments in excess of the allowable amount for an identified covered service.
- Errors and nonreimbursable expenditures in cost reports.
- Duplicate payments.
- Receipt of Medicare payment when another payor had the primary

responsibility for payment.

In certain circumstances, Medicare makes estimated payments for services with the knowledge that a reconciliation of those payments to actual costs will be done when the actual costs or related information becomes available, usually at a later date. Interim payments made to a provider throughout the cost year are reconciled with covered and reimbursable costs at the time the cost report is due. The statutory and proposed regulatory definition of the term overpayment acknowledges this practice and provides that an overpayment does not exist until after an applicable reconciliation takes place. When a provider files a cost report, the provider is attesting to the accuracy of the information contained on the cost report and must maintain the appropriate documentation supporting the costs that are claimed on the cost report. We rely upon the information that providers submit through the cost report and we believe that providers must accurately report any overpayments at the time they submit any cost reports to CMS – whether it is an initial submission of a cost report or an amended one.

2. Medicare Contractor

We propose that the term "Medicare contractor" means a fiscal intermediary, carrier, durable medical equipment Medicare administrative contractor (DME MAC), or Part A/Part B Medicare administrative contractor. We believe that this proposed definition captures the different contractors that would be involved in receiving reports of overpayments as well as handling the return of overpayments, consistent with the statutory requirement.

3. Person

We propose that a person means a provider (as defined in §400.202) or supplier (as defined in §400.202). This definition does not include a beneficiary. Our proposal is consistent with the definition of a "person" in section 1128J(d) of the Act.

C. Requirements for Reporting and Returning of Overpayments (Proposed §401.305)

1. General

Section 1128J of the Act provides that if a person has received an overpayment, the person shall "(i) report and return the overpayment to the Secretary... an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and (ii) notify the Secretary... intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment."

We propose to implement these requirements by using the existing voluntary refund process, which will be renamed the "self-reported overpayment refund process." This process is described in Publication 100-06, Chapter 4 of the Medicare Financial Management Manual. Under the existing voluntary refund process, providers and suppliers report overpayments using a form that each Medicare contractor makes available on its website. The form requires that providers and suppliers provide information to allow CMS to identify the affected claims, such as the health insurance claim number (HICN); the provider's or supplier's name, number and tax identification number; and the date of service. The voluntary refund process also requires providers and suppliers to summarize why the refund is being made including the following information: (1) how the error was discovered; (2) a description of the corrective action plan implemented to ensure the error does not occur again; (3) the reason for the refund; (4) whether the provider or supplier has a corporate integrity agreement (CIA) with the

OIG or is under the OIG Self-Disclosure Protocol; (5) the timeframe and the total amount of refund for the period during which the problem existed that caused the refund; (6) Medicare claim control number, as appropriate; (7) Medicare National Provider Identification (NPI) number; (8) a refund in the amount of the overpayment; and (9) if a statistical sample was used to determine the overpayment amount, description of the statistically valid methodology used to determine the overpayment. We are proposing that providers and suppliers would be required to use the self-reported overpayment refund process set forth by the applicable Medicare contractor to report and return overpayments.

Some clarification may be helpful in defining potential reasons for an overpayment since such information must be reported under section 1128J(d) of the Act. While we cannot provide an exhaustive list of all potential reasons for the overpayment as required to be reported at §401.305(d), we can provide examples. Examples of what a person may report as the reason for the overpayment include the following: (1) incorrect service date; (2) duplicate payment; (3) incorrect CPT code; (4) insufficient documentation; and (5) lack of medical necessity. We note that many of the forms currently available from our contractors provide a "check the box" format that allows providers and suppliers to easily identify the reason for the overpayment. For overpayments that are not listed on the form that is available from the Medicare contractor, there is an associated "other" box that allows providers and suppliers to clarify the reason for the overpayment.

We make these proposals because we believe that the information requested under the existing voluntary refund process, such as the date of service and the HICN, is

necessary to allow CMS to appropriately match claims information with the information that is reported by the provider or supplier and to understand the nature of the overpayment. Furthermore, we recognize that the reporting forms may differ among the different Medicare contractors and plan to develop a uniform reporting form that will enable all overpayments to be reported and returned in a consistent manner across all Medicare contractors. Until such uniform reporting form is made available, providers and suppliers should utilize the existing form available from the website of the applicable Medicare contractor as discussed earlier in this proposed rule.

2. Identified

Section 1128J of the Act provides that the terms 'knowing' and 'knowingly' have the meaning given those terms in the False Claims Act (31 U.S.C. 3729(b)(3)). The statutory text, however, does not use this phrase other than in the definitions. In §401.305 (a)(2), we propose that a person has identified an overpayment if the person has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment. We believe Congress' use of the term "knowing" in the ACA was intended to apply to determining when a provider or supplier has identified an overpayment. We believe defining "identification" in this way gives providers and suppliers an incentive to exercise reasonable diligence to determine whether an overpayment exists. Without such a definition, some providers and suppliers might avoid performing activities to determine whether an overpayment exists, such as self-audits, compliance checks, and other additional research.

3. Reporting and Returning Deadlines

Section 1128J of the Act provides that an overpayment must be reported and returned by the later of --(i) the date which is 60 days after the date on which the overpayment was identified; or (ii) the date any corresponding cost report is due, if applicable. Proposed §401.305(b) contains an identical requirement. If an overpayment is claims related, the provider or supplier would be required to report and return the overpayment within 60 days of identification. However, for those providers that submit cost reports, if the overpayment is such that it would generally be reconciled on the cost report by the provider, the provider would be permitted to report and return the overpayment either 60 days from the identification of the overpayment or on the date the cost report is due, whichever is later. For example, issues involving upcoding must be reported and returned within 60 days of identification because the upcoded claims for payment are not submitted to Medicare in the form of cost reports. However, for an overpayment that would generally be reconciled on the cost report, such as overpayments related to graduate medical education payments, the provider must report and return the overpayment either 60 days after it has been identified or on the date the cost report is due, whichever is later. We believe that the qualifying language "if applicable" supports the proposed approach of only permitting providers to rely upon the cost report deadline when relevant to the determination of whether an actual overpayment exists. We make this clarification to avoid situations in which providers improperly delay reporting and returning a claims-related, identified overpayment until the date a cost report is due. We do not believe that Congress intended to create a loophole that would allow providers to delay reporting and returning an identified overpayment until a cost report is due if the overpayment would not ordinarily be reconciled on the cost report.

The proposed 60-day requirement to report and return overpayments would run from the date on which the person had identified the overpayment. As previously discussed, an overpayment has been identified at the time that a person acts with actual knowledge of, in deliberate ignorance of, or with reckless disregard to the overpayment's existence. In some cases, a provider or supplier may receive information concerning a potential overpayment that creates an obligation to make a reasonable inquiry to determine whether an overpayment exists. If the reasonable inquiry reveals an overpayment, the provider then has 60 days to report and return the overpayment. On the other hand, failure to make a reasonable inquiry, including failure to conduct such inquiry with all deliberate speed after obtaining the information, could result in the provider knowingly retaining an overpayment because it acted in reckless disregard or deliberate ignorance of whether it received such an overpayment. For example, a provider that receives an anonymous compliance hotline telephone complaint about a potential overpayment has incurred an obligation to timely investigate that matter. If the provider diligently conducts the investigation, and reports and returns any resulting overpayments within the 60-day reporting and repayment period, then the provider would have satisfied its obligations under the proposed rule. If, however, the provider fails to make any reasonable inquiry into the complaint, the provider may be found to have acted in reckless disregard or deliberate ignorance of any overpayment.

In order to assist providers and suppliers with understanding when an overpayment has been identified, we provide the following examples:

- A provider of services or supplier reviews billing or payment records and learns that it incorrectly coded certain services, resulting in increased reimbursement.

- A provider of services or supplier learns that a patient death occurred prior to the service date on a claim that has been submitted for payment.
- A provider of services or supplier learns that services were provided by an unlicensed or excluded individual on its behalf.
- A provider of services or supplier performs an internal audit and discovers that overpayments exist.
- A provider of services or supplier is informed by a government agency of an audit that discovered a potential overpayment, and the provider or supplier fails to make a reasonable inquiry. (When a government agency informs a provider or supplier of a potential overpayment, the provider or supplier has an obligation to accept the finding or make a reasonable inquiry. If the provider's or supplier's inquiry verifies the audit results, then it has identified an overpayment and, assuming there is no applicable cost report, has 60 days to report and return the overpayment. As noted previously, failure to make a reasonable inquiry, including failure to conduct such inquiry with all deliberate speed after obtaining the information, could result in the provider or supplier knowingly retaining an overpayment because it acted in reckless disregard or deliberate ignorance of whether it received such an overpayment).
- A provider of services or supplier experiences a significant increase in Medicare revenue and there is no apparent reason – such as a new partner added to a group practice or a new focus on a particular area of medicine – for the increase. Nevertheless, the provider or supplier fails to make a reasonable inquiry into whether an overpayment exists. (When there is reason to suspect an overpayment, but a provider or supplier fails to make a reasonable inquiry into whether an overpayment exists, it may be

found to have acted in reckless disregard or deliberate ignorance of any overpayment.)

We emphasize that these examples are not an exhaustive list of situations where a person has identified an overpayment.

We recognize that there are also intersections between the obligation to report and return overpayments under section 6402(a) of the Affordable Care Act and the existing procedures for providers and suppliers to self-disclose actual or potential violations of the physician self-referral statute to CMS through the Medicare Self-Referral Disclosure Protocol (SRDP). Providers and suppliers self-disclose violations under the SRDP with the intention of resolving overpayment liability exposure for the identified conduct. The SRDP is available on the CMS website at

https://www.cms.gov/PhysicianSelfReferral/Downloads/6409_SRDP_Protocol.pdf.

Under the SRDP, we may reduce the amount due and owing for violations of the physician self-referral statute. We have suspended the obligation to return overpayments under section 6402(a) of the Affordable Care Act when we acknowledge receipt of a disclosure made pursuant to the process established by the SRDP. Because the SRDP only suspends the running of the 60-day deadline to return a physician self-referral-related overpayment, the provider or supplier would be obligated still to report the overpayment using the process that we are proposing in §401.305(a)(1). Specifically with regard to the SRDP, we seek comment on alternative approaches that would allow providers and suppliers to avoid making multiple reports of identified overpayments.

We note that there are also intersections between the obligation to report and return an overpayment under section 6402(a) of the Affordable Care Act and the existing procedures for reporting self-discovered evidence of potential fraud to the OIG through

the OIG Self-Disclosure Protocol (OIG SDP). The OIG SDP is available on the OIG website at <http://oig.hhs.gov/authorities/docs/selfdisclosure.pdf>. Disclosures resolved through the OIG SDP result in a settlement with OIG that releases the OIG's applicable Civil Monetary Penalties Law (CMPL) and permissive exclusion authorities in exchange for a negotiated monetary payment that includes the overpayment as well as certain penalties and assessments. In §401.305(b), we propose to suspend the obligation to return overpayments under section 6402(a) of the Affordable Care Act when OIG acknowledges receipt of a submission to the OIG SDP. The obligation to return overpayments consistent with the processes established in this proposed rule would be suspended until a settlement agreement is entered, or the provider or supplier withdraws or is removed from the OIG SDP. We also propose that once the provider or supplier notifies OIG of the identified overpayment through the OIG SDP, such notice would constitute a report for purposes of the reporting requirement set forth at §401.305 of this proposed rule. However, we note that such reports must be made in accordance with the timeliness requirements set forth at §401.305.

Providers and suppliers should ensure that they are using the most appropriate process to report and return overpayments. In the October 30, 1998 **Federal Register**, (63 FR 58400) the OIG published a notice stating --

[the SDP] is intended to facilitate the resolution of only matters that, in the provider's reasonable assessment, are potentially violative of Federal, criminal, civil or administrative laws. Matters exclusively involving overpayments or errors that do not suggest that violations of law have occurred should be brought directly to the attention of the entity (e.g. a contractor such as a carrier or an intermediary) that processes claims and issues payment on behalf of the Government agency responsible for the particular Federal health care program (e.g., [CMS] for

matters involving Medicare). The program contractors are responsible for processing the refund and will review the circumstances surrounding the initial overpayment. If the contractor concludes that the overpayment raises concerns about the integrity of the provider, the matter may be referred to the OIG. Accordingly, the provider's initial decision of where to refer a matter involving non-compliance with program requirements should be made carefully.

We believe the distinctions drawn previously are relevant because the process of reporting and returning overpayments pursuant to section 1128J of the Act cannot resolve any potential False Claims Act or OIG administrative liability associated with the overpayment (even though returning an overpayment may, among other benefits, limit any FCA or administrative liability arising from the retention of an overpayment). Providers and suppliers should be aware that the contractors will scrutinize overpayments received through this process and may make referrals to OIG whenever the contractors believe circumstances warrant such a referral.

We are aware that providers and suppliers may be concerned about scenarios in which they have identified an overpayment but because of the magnitude of the overpayment, need additional time to make repayment. Providers and suppliers may not delay the identification date in these situations to meet the deadline prescribed for reporting and returning the overpayment. Instead, if a provider or supplier needs additional time due to financial constraints, the provider or supplier must use the existing Extended Repayment Schedule (ERS)¹ process that is outlined in Publication 100-06, Chapter 4 of the Financial Management Manual. Because the statute is clear as to the deadline for reporting and returning overpayments, we believe that using the existing

¹ The "Extended Repayment Schedule" was formerly referred to as the "Extended Repayment Plan."

ERS process would be the best means of addressing potential financial limitations associated with the ability to repay the overpayment. We note that requests for ERS are not automatically granted and that providers and suppliers seeking to repay an identified overpayment using the ERS are required to submit significant documentation to allow CMS to verify that timely repayment of the overpayment represents a true financial hardship to the provider or supplier. The ERS is the only means by which extended repayment of an overpayment will be permitted. We propose to amend the definition of "hardship" at §401.607 to ensure that providers and suppliers can seek to utilize the ERS to return identified overpayments for purposes of section 1128J(d) of the Act when financial constraints suggest that use of the ERS is appropriate.

Finally, we note the following with regard to overpayments that arise due to a violation of the anti-kickback statute (section 1128B(b)(1) and (2) of the Act). Compliance with the anti-kickback statute is a condition of payment. Claims that include items and services resulting from a violation of this law are not payable and constitute false or fraudulent claims for purposes of the False Claims Act. We recognize that, in many instances, a provider or supplier is not a party to, and is unaware of the existence of, an arrangement between third parties that causes the provider or supplier to submit claims that are the subject of a kickback. For example, a hospital may be unaware that a device manufacturer has paid a kickback to a physician on the hospital's medical staff to induce the physician to implant the manufacturer's device in procedures performed at the hospital. Moreover, even if a provider or supplier becomes aware of a potential third party payment arrangement, it would generally not be able to evaluate whether the

payment was an illegal kickback or whether one or both parties had the requisite intent to violate the anti-kickback statute.

For this reason, we believe that providers who are not a party to a kickback arrangement are unlikely in most instances to have "identified" the overpayment that has resulted from the kickback arrangement and would therefore have no duty to report it or, as discussed later in this section, to repay it. To the extent that a provider or supplier who is not a party to a kickback arrangement has sufficient knowledge of the arrangement to have identified the resulting overpayment, the provider or supplier must report the overpayment to CMS in accordance with section 1128J(d) of the Act and corresponding regulations. Although the government may always seek repayment of claims paid that do not satisfy a condition of payment, where a kickback arrangement exists, HHS's enforcement efforts would most likely focus on holding accountable the perpetrators of that arrangement. Accordingly, we would refer the reported overpayment to OIG for appropriate action and would suspend the repayment obligation until the government has resolved the kickback matter (either by determining that no enforcement action is warranted or by obtaining a judgment, verdict, conviction, guilty plea, or settlement). Thus, if the provider has not identified the kickback or if it reported it when it did identify the kickback, our expectation is that only the parties to the kickback scheme would be required to repay the overpayment that was received by the innocent provider or supplier, except in the most extraordinary circumstances.

4. Applicable Reconciliation

As previously noted, the statutory and our proposed regulatory definition of an overpayment acknowledges that, in some instances, we make interim payments to a

provider through the cost year and that the provider reconciles these payments with covered and reimbursable costs at the time the cost report is due. In §401.305(c), we propose that "applicable reconciliation" will occur with the provider's submission of a cost report. We believe that this would include an initial cost report submission or an amended cost report. We expect providers to accurately report and return overpayments at these points in time, because we rely upon the information that providers include on cost reports.

We propose to recognize two exceptions to the general rule that the applicable reconciliation occurs with the provider's submission of a cost report. The first exception is related to Supplemental Security Income (SSI) ratios used in the calculation of disproportionate share hospital (DSH) payment adjustment. We publish these ratios annually on our website and providers are expected to use the appropriate ratio when submitting the cost report for that cost year, unless the published ratios are not available at the time the cost report is due. In instances where the provider later receives more recent information regarding its SSI ratio, we propose that the provider would not be required to amend the cost report or calculate the change in reimbursement and return the potential overpayment until the final reconciliation of the provider's cost report occurs. The second exception is related to the outlier reconciliation. We perform an outlier reconciliation at the time the cost report is settled if certain thresholds are exceeded. Prior to this reconciliation the actual amount of any overpayment is not known. In instances where the provider is aware it has exceeded the established thresholds and an outlier reconciliation will be performed, we propose that the provider would not be required to estimate the change in reimbursement and return the estimated overpayment

until the final settlement of that cost report.

5. Enforcement

Section 1128J(d) of the Act provides that any overpayment retained by a person after the deadline for reporting and returning the overpayment is an obligation for purposes of 31 U.S.C. 3729. Any person who "knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government" may be found liable under the False Claims Act. (See 31 U.S.C. 3729 et seq.) Proposed §401.305(f) contains a similar statement. Additionally, any person who "knows of an overpayment [as defined in section 1128J(d)(4) of the Act] and does not report and return the overpayment in accordance with such section" may be found liable under the Civil Monetary Penalties Law (section 1128A(a)(10) of the Act) and accordingly could be excluded from participation in Federal health care programs (section 1128A of the Act).

6. Lookback Period and Related Issues

In §401.305(g), we are proposing that overpayments must be reported and returned only if a person identifies the overpayment within 10 years of the date the overpayment was received. We selected 10 years because this is the outer limit of the False Claims Act statute of limitations. We believe that the proposed 10-year lookback period is appropriate for several reasons. First, we believe that providers and suppliers should have certainty after a reasonable period that they can close their books and not have ongoing liability associated with an overpayment. We also believe that the length of the lookback period is long enough to sufficiently further our interest in ensuring that overpayments are timely returned to the Medicare Trust Funds.

We propose to amend the reopening rules at §405.980(b) to provide that overpayments reported in accordance with §401.305 may be reopened for a period of 10 years. We make this proposal in order to ensure that our reopening regulations are consistent with the lookback period that we are proposing. We seek comment on the proposed 10-year lookback period. In addition, we seek comment on our proposal to amend the reopening rules to provide for a 10-year reopening period.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day 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. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 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 information collection requirements (ICRs):

Proposed §401.305 states that a provider or supplier must report and return an overpayment to the Secretary, the State, an intermediary, a carrier or a contractor to the

correct address by the later of 60 days after the overpayment was identified or the date the corresponding cost report is due and notify the Secretary, the State, an intermediary, a carrier or a contractor in writing of the reason for the overpayment. The burden associated with this requirement would be the time and effort necessary to report and return the overpayment in the manner described at §401.305.

For purposes of this section only, we estimate that approximately 125,000 providers and suppliers (or roughly 8.5 percent of the total number of Medicare providers and suppliers) would report and return overpayments in a typical year under our proposed provisions. In addition, we project that each of these providers and suppliers would, on average, separately report and return approximately 3 to 5 overpayments. We also estimate that it would take a provider or supplier approximately 2.5 hours to complete the applicable reporting form and return an overpayment. Lastly, the two main categories of individuals believed to complete and submit the applicable reporting form include: (1) accountants and auditors (external and in-house); and (2) miscellaneous in-house administrative personnel. Each provider and supplier's individual operations is different and, as a result, it is not possible to break down the percentage of total affected providers of suppliers that would fall within the two aforementioned categories (for example, percentage of providers that would use an accountant). Consequently, in order to determine the burden cost, we utilize the average hourly wage of these two occupational categories based on the most recent wage data provided by the Bureau of Labor Statistics (BLS) data for May 2010. The mean hourly wage for the category of "accountants and auditors" is \$33.15 (see <http://www.bls.gov/oes/current/oes132011.htm>) and the mean hourly wage for the category of "bookkeeping, accounting, and auditing clerks" is \$16.99

(<http://www.bls.gov/oes/current/oes433031.htm>). The average of these two figures, including fringe benefits and overhead, is \$37.10. This, in turn, leads to an aggregate annual ICR burden cost, attributable to the impacted 125,000 providers and suppliers for the range of 3 to 5 overpayments, of \$34.78 million and \$57.97 million, respectively. Again these are rough estimates, as the number of overpayments reported and returned will vary per provider and supplier. Therefore, we solicit comment on our burden assumptions and associated calculations.

Table 1: Annual Burden Requirements and Costs Associated with Reporting and Returning of Overpayments (\$401.305)

Number of Impacted Providers and Suppliers	Number of Overpayments Processed per Provider and Supplier	Burden per Overpayment Reported and Returned (Hours)	Total Annual Burden (Hours)	Hourly Labor Cost of Reporting	Total Cost (in millions)
125,000	3-5	2.5	937,500 – 1,562,500	\$37.10	\$34.78 - \$57.97

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the "ADDRESSES" section of this proposed rule; or
2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [CMS-6037-P]

Fax: (202) 395-5806; or

Email: OIRA_submission@omb.eop.gov

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually.

We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

A. Statement of Need

This proposed rule is necessary to implement section 6402(a) of the Affordable Care Act, which established a new section 1128J(d) of the Act entitled "Reporting and Returning of Overpayments." 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, at the correct address, and to notify the Secretary, State, intermediary, carrier or contractor to whom the overpayment was returned in writing of the reason for the overpayment. Section 1128J(d)(2) of the Act requires that an overpayment must be reported and returned by the later of-- (1) the date which is 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 (as defined in 31 U.S.C. 3729(b)(3)) for purposes of 31 U.S.C. 3729. As a result, this proposed rule clarifies to providers and suppliers their legal obligations regarding the reporting and returning of overpayments.

A. Overall Impact

We have examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulation impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any one year).

As discussed earlier in the preamble, even without a final regulation, all stakeholders are subject to the statutory requirements found in section 1128J(d) of the Act and could face potential False Claims Act liability, Civil Monetary Penalties Law liability, and exclusion from Federal health care programs for failure to report and return an overpayment. This proposed rule would impose a new deadline on the return of any overpayment that has been identified. We believe that this change would spur providers to be more diligent in reporting and returning overpayments. That will likely increase the overpayments that we collect, but we do not have a basis for estimating the magnitude of

that change, and note the substantial uncertainty surrounding the magnitude of new collections. The burden costs for reporting and returning of overpayments, as discussed in section III. of this proposed rule, are estimated annually between \$34.78 million to \$57.97 million. As a result, this proposed rule is not an economically significant rule under Executive Order 12866. We solicit comment on the analysis and conclusions provided in the RIA.

The RFA requires agencies to analyze options for regulatory relief for small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business and having revenues of less than \$7 million to \$34.5 million in any 1 year. (For details, see the Small Business Administration's Table of Size Standards at http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf.) Individuals and States are not included in the definition of a small entity. We do not believe that the reporting and returning of overpayments identified by providers and suppliers of services will have a significant impact on a substantial number of small entities. The requirements of this rule add another program integrity tool, but do not replace existing overpayment recovery efforts. We are not preparing an analysis for the RFA because the Secretary has determined that this proposed rule will not have a significant impact on a substantial number of small entities.

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 RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital located outside of the Metropolitan Statistical Area and has fewer than 100 beds. The cost of the required reporting should be minimal for small rural hospitals because standard business practices dictate keeping accurate records concerning monies due and/or payable. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$136 million. This proposed rule would have no effect on the annual expenditures of any State, local or tribal government, or the private sector.

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 cost on State and local governments, preempts State law, or otherwise has Federalism implications. Since this proposed rule does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

C. Alternatives Considered

In light of the statutory mandate in section 6402(a) of the Affordable Care Act, we did not consider any alternatives to the implementation of this provision. We did,

however, contemplate several operational mechanisms to alleviate the burden on the provider and supplier communities.

First, we considered and elected to utilize the existing voluntary refund process. This would allow providers and suppliers to use a reporting mechanism with which they are already familiar.

Second, we contemplated the appropriate length of time in which overpayments must be reported and returned. A time period of less than 10 years was considered, as this would ease the burden on providers and suppliers. However, and as explained earlier, we selected 10 years because this is the outer limit of the False Claims Act statute of limitations. More importantly, we believe that the need to protect the Medicare Trust Fund was of primary importance. It is not possible for us to calculate the costs associated with a 10-year period versus, for instance, a 5-year period. We do, though, solicit comments on this issue, similar to our earlier solicitation of comments on the propriety of a 10-year period.

Third, as with the overpayment reporting period, we contemplated a reopening timeframe of less than 10 years. Yet we selected a 10-year timeframe in order to ensure that our reopening regulations are consistent with the 10-year lookback period. The costs of a shorter lookback period cannot be estimated, though we welcome comments on this issue.

We solicit comment on the analysis provided in this section.

D. Beneficiary Access

We do not anticipate any impact on beneficiary access to care as a result of this proposed rule. As mentioned, the only burden associated with our proposed provisions

involves the ICR aspects of reporting and returning overpayments. We do not believe that this burden – which, in any event, would only affect a small percentage of providers and suppliers – would cause a particular provider or supplier to reduce the services it furnishes to beneficiaries.

List of Subjects

42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions,
Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements,
Rural areas, X-rays.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend Chapter IV as set forth below:

PART 401--GENERAL ADMINISTRATIVE REQUIREMENTS

1. The authority citation for part 401 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. Part 401 is amended by adding subpart D to read as follows:

Subpart D --Reporting and Returning of Overpayments

Sec.

401.301 Basis and scope.

401.303 Definitions.

401.305 Requirements for reporting and returning of overpayments.

§401.301 Basis and scope.

This subpart sets forth the policies and procedures for reporting and returning overpayments to the Medicare program for providers and suppliers of services under Parts A and B of title XVIII of the Act as required by section 1128J of the Act.

§401.303 Definitions.

For purposes of this subpart--

Medicare contractor means a fiscal intermediary, carrier, durable medical equipment Medicare administrative contractor (DME MAC), or Part A/Part B Medicare administrative contractor.

Overpayment means any funds that a person has received or retained under title XVIII of the Act to which the person, after applicable reconciliation, is not entitled under such title.

Person means a provider (as defined in §400.202) or a supplier (as defined in §400.202).

§401.305 Requirements for reporting and returning of overpayments.

(a) General. (1) If a person has identified that it has received an overpayment the person must report and return the overpayment in the form and manner set forth in this section.

(2) A person has identified an overpayment if the person has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the existence of the overpayment.

(b) Deadline for reporting and returning overpayments. (1) A person with an identified overpayment must report and return the overpayment by the later of either of the following:

(i) The date which is 60 days after the date on which the overpayment was identified.

(ii) The date any corresponding cost report is due, if applicable.

(2) The deadline for returning overpayments will be suspended when either of the following occurs:

(i) OIG acknowledges receipt of a submission to the OIG Self-Disclosure Protocol until such time as a settlement agreement is entered, the person withdraws from

the OIG Self-Disclosure Protocol, or the person is removed from the OIG Self-Disclosure Protocol.

(ii) CMS acknowledges receipt of a submission to the Self-Referral Disclosure Protocol until such time as a settlement agreement is entered, the person withdraws from the Self-Referral Disclosure Protocol, or the person is removed from the Self-Referral Disclosure Protocol.

(c) Applicable reconciliation. (1) The applicable reconciliation occurs when a cost report is filed; and

(2) In instances when the provider --

(i) Receives more recent CMS information on the SSI ratio, the provider is not required to return any overpayment resulting from the updated information until the final reconciliation of the provider's cost report occurs; or

(ii) Knows that an outlier reconciliation will be performed, the provider is not required to estimate the change in reimbursement and return the estimated overpayment until the final reconciliation of that cost report.

(d) Contents of report. An overpayment required to be reported under this section to a Medicare contractor must be made in writing and must contain all of the following:

(1) Person's name.

(2) Person's tax identification number.

(3) How the error was discovered.

(4) The reason for the overpayment.

(5) The health insurance claim number, as appropriate.

(6) Date of service.

(7) Medicare claim control number, as appropriate.

(8) Medicare National Provider Identification (NPI) number.

(9) Description of the corrective action plan to ensure the error does not occur again.

(10) Whether the person has a corporate integrity agreement with the OIG or is under the OIG Self-Disclosure Protocol.

(11) The timeframe and the total amount of refund for the period during which the problem existed that caused the refund.

(12) If a statistical sample was used to determine the overpayment amount, a description of the statistically valid methodology used to determine the overpayment.

(13) A refund in the amount of the overpayment. A person may request an extended repayment schedule as that term is defined in § 401.603.

(e) Reporting. (1) A person must use the self-reported overpayment refund process set forth by the applicable Medicare contractor to report and return overpayments except as provided in paragraph (e)(2) of this section.

(2) A person satisfies the reporting obligations of this section by making a disclosure under the OIG's Self-Disclosure Protocol resulting in a settlement agreement using the process described in the OIG Self-Disclosure Protocol.

(f) 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 31 U.S.C. 3729.

(g) Lookback period. An overpayment must be reported and returned in

accordance with § 401.305 only if a person identifies the overpayment within 10 years of the date the overpayment was received.

Subpart F--Claims Collection and Compromise

§401.607 [Amended]

3. In §401.607(c)(2)(i), the definition of "Hardship" is amended by removing the phrase "outstanding overpayments (principal and interest)" and adding in its place the phrase "outstanding overpayments (principal and interest and including overpayments reported in accordance with §§ 401.301 through 401.305.)"

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

4. The authority for part 405 continues to read as follows:

Authority: Secs. 1102, 1862, and 1871 of the Social Security Act as amended (42 U.S.C.1302, 1395y, and 1395hh).

5. Section 405.980 is amended by adding paragraph (b)(6) to read as follows:

§405.980 Reopenings of initial determinations, redeterminations, and reconsiderations, hearings and reviews.

* * * * *

(b) * * *

(6) Within 10 years from the date of initial determination or redetermination if the overpayment is reported in accordance with § 401.305.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program)

Dated: August 18, 2011

Donald M. Berwick,
Administrator,
Centers for Medicare & Medicaid Services.

Approved: February 10, 2012

Kathleen Sebelius,
Secretary,
Department of Health and Human Services.

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