DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 401 and 405

[CMS–6037–F]

RIN 0938–AQ58

Medicare Program; Reporting and Returning of Overpayments

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

ACTION: Final rule.

SUMMARY: This final rule requires providers and suppliers receiving funds under the Medicare program to report and return overpayments by the later of the date that is 60 days after the date on which the overpayment was identified; or the date any corresponding cost report is due, if applicable. The requirements in this rule 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. This rule provides needed clarity and consistency in the reporting and returning of self-identified overpayments.

DATES: These regulations are effective on March 14, 2016.

FOR FURTHER INFORMATION CONTACT: Joe Strazzire, (410) 786–2775.

SUPPLEMENTARY INFORMATION:

I. Executive Summary and Background

A. Executive Summary

1. Purpose

On March 23, 2010, the Affordable Care Act was enacted. Section 6402(a) of the Affordable Care Act established a new section 1128J(d) of the Social Security Act (the Act). 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—(A) the date which is 60 days after the date on which the overpayment was identified; or (B) 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.

The requirements in this rule 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. This rule provides needed clarity and consistency in the reporting and returning of self-identified overpayments. However, even without this final rule, providers and suppliers are subject to the statutory requirements found in section 1128J(d) of the Act and could face potential False Claims Act (FCA) liability, Civil Monetary Penalties Law (CMPL) liability, and exclusion from federal health care programs for failure to report and return an overpayment. Additionally, providers and suppliers continue to be required to comply with our current procedures [1] when we, or our contractors, determine an overpayment and issue a demand letter.

2. Summary of the Major Provisions

a. Meaning of Identification

Section 1128J(d) 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. This final rule states that a person has identified an overpayment when the person has or should have, through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. Creating this standard for identification provides needed clarity and consistency for providers and suppliers on the actions they need to take to comply with requirements for reporting and returning of self-identified overpayments.

b. Lookback Period

This final rule states that overpayments must be reported and returned only if a person identifies the overpayment within 6 years of the date the overpayment was received. Creating this limitation for how far back a provider or supplier must look when identifying an overpayment is necessary in order to avoid imposing unreasonable additional burden or cost on providers and suppliers.

[1] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/MLN-Publications-Items/CMS1243389.html.*

c. How to Report and Return Overpayments

This final rule states that providers and suppliers must use an applicable claims adjustment, credit balance, self-reported refund, or another appropriate process to satisfy the obligation to report and return overpayments. This position preserves our existing processes and preserves our ability to modify these processes or create new processes in the future.

3. Summary of Costs and Benefits

This final rule states that a provider or supplier must (1) 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 (2) notify the Secretary, the state, an intermediary, a carrier, or a contractor in writing of the reason for the overpayment. The costs associated with these requirements are the time and effort necessary for providers and suppliers to identify, report, and return overpayments in the manner described in this rule. We project an annual cost burden of between $120.87 million and $201.45 million. The former represents our low-end estimate, while the latter is our high-end estimate. Our primary, or mid-range, projection is an estimate of $161.16 million.

The requirements in this final rule 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. The potential financial benefits of this final rule from the standpoint of its effectiveness in recouping overpayments are not easily quantifiable, as we do not have sufficient data on which to base a monetary estimate of recovered funds.

B. Background

The Medicare program (title XVIII of the Act) is the primary payer of health care for approximately 50 million enrolled beneficiaries. Providers and suppliers furnishing Medicare items and services must comply with the Medicare requirements set forth in the Act and in CMS 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 part of our efforts to reduce fraud, waste, and abuse in the Medicare program, we twice proposed, but did

not finalize, rules that would have amended our regulations to codify the longstanding responsibility of persons to report and return Medicare overpayments. (See the March 25, 1998 (63 FR 14506) and January 25, 2002 (67 FR 3662) proposed rules.)

On March 23, 2010, the Affordable Care Act was enacted. Section 6402(a) of the Affordable Care Act established a new section 1128J(d) of the Act. 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—(A) the date which is 60 days after the date on which the overpayment was identified; or (B) 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) of the Act defines ''knowing'' and ''knowingly'' as those terms are defined in 31 U.S.C. 3729(b). In that statute 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. 31 U.S.C. 3729(b) also states that knowing and knowingly do not require 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. Lastly, 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 (MA) organization (as defined in section 1859(a)(1) of the Act) or prescription drug plan (PDP) sponsor (as defined in section 1860D–41(a)(13) of the Act). Section 1128J(d)(4)(C) of the Act excludes beneficiaries from the definition of person.

In the February 16, 2012 **Federal Register** (77 FR 9179), we published a proposed rule that would implement the provisions of section 1128J(d) of the Act.

II. Provisions of the Proposed Regulations and Analysis of and Responses to Public Comments

To implement section 1128J(d) of the Act, we proposed to establish a new subpart D in part 401 of our regulations, to revise § 401.607, and to add sections to part 405 of our regulations. In response to the February 16, 2012 proposed rule, we received approximately 200 timely pieces of correspondence. In this section of this final rule, we summarize our proposals, respond to the public comments received, and detail the changes made to our proposals.

Many commenters stated their support for many provisions and goals of the proposed rule. Commenters generally agreed that providers and suppliers should promptly refund overpayments and maintain efforts to prevent and detect improper payments. While these commenters also suggested changes to certain provisions of the proposed rule, commenters stated that many of the proposed rule's requirements were reasonable. Some commenters stated they were pleased that CMS issued the proposed rule and believed it would motivate providers and suppliers to educate billing staff and practitioners on Medicare billing rules. These commenters stated they were hopeful that the rule would reduce improper payments and would help ensure the viability of the Medicare Trust Funds. Overall, we appreciate the comments expressing support for as well as the comments suggesting changes to the proposed rule.

A. Scope of Subpart (Proposed § 401.301)

In proposed § 401.301, we stated 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. We proposed 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, MA organizations, PDPs, and Medicaid MCOs would be addressed in future rulemaking. Since then, in the May 23, 2014 **Federal Register** (79 FR 29844), we published a final rule that addresses Medicare Parts C and D. No final rule has been published that addresses Medicaid requirements

Comment: A number of commenters expressed concern over the limitation of the proposed rule to Medicare Parts A and B. Commenters stated that CMS did not articulate any statutory authority or rationale for creating this distinction and narrowing the scope of the proposed rule to Medicare Part A and Part B providers and suppliers. According to commenters, the Medicare payment rules do not create any analytically distinct issues for Medicare Part A and Part B providers and suppliers over other categories of ''persons'' as defined under the proposed rule, thus commenters believed that the rule should similarly apply equally to all categories of persons as they relate to Medicare. Commenters noted that many providers or suppliers who submit claims to Medicare Part A or B also submit claims to managed care plans under Part C, plan sponsors under Part D, and Medicaid. Commenters requested that CMS include all of Medicare and Medicaid in the final rule or quickly issue other proposed rules so all providers and suppliers have guidance on their obligations and are treated equally.

Response: Given the differences that exist between Medicare Parts A and B and Medicare Parts C and D and Medicaid, we believe that separate rulemaking processes are appropriate to address those differences. Those differences include, but are not limited to, how the programs are administered and the involvement of Medicare contractors in Part A and B, private health insurance plans in Part C, PDP sponsors in Part D, and state Medicaid agencies and contractors in Medicaid. The Secretary has the programmatic rulemaking authority to issue regulations on section 1128J(d) of the Act. We note that section 1128J(d) of the Act does not require the Secretary to issue regulations for the statute to be effective, and the statute's requirements are in effect in the absence of regulation. Providers and suppliers that identify overpayments received from Medicare or Medicaid should report and return those overpayments to the appropriate payor as required by section 1128J(d) of the Act. We appreciate commenters' concerns, but will finalize this rule as proposed to apply to Medicare Parts A and B only. Additionally, our rules for reporting and returning of overpayments in Medicare Parts C and D were recently published in separate rulemaking (see the May 23, 2014 final rule (79 FR 29843)).

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 FCA liability, CMPL liability, and exclusion from federal health care programs for failure to report and return an overpayment. Additionally, providers and suppliers continue to be required to comply with our current procedures when we, or our contractors, determine an overpayment and issue a demand letter.

B. Definitions (Proposed § 401.303)

We proposed three definitions in § 401.303. We proposed to define ''Medicare contractor'' as a fiscal intermediary, carrier, durable medical equipment Medicare administrative contractor (DME MAC), or Part A/Part B Medicare administrative contractor. We stated that our 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. Since the publication of the proposed rule, we have ceased using fiscal intermediary and carrier contracts, and accordingly we have removed these terms from the definition of ''Medicare contractor'' in the final rule.

''Overpayment'' was proposed to be defined as 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. This is the same definition that appears in the statute. In section II.B. of the February 2012 proposed rule (77 FR 9181), we also included certain examples of overpayments under this proposed definition as including 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.

We also stated in the proposed rule that, 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 reporting the provider's reconciliation described previously and attesting to the accuracy of the information contained on the cost report. Providers must maintain the appropriate documentation supporting the costs that are claimed on the cost report. We stated that we rely upon the information that providers submit through the cost report. Whether it is an initial submission of a cost report or an amended one, we believed that providers must accurately report any cost report-related overpayments at the time they submit any cost reports to CMS.

Finally, we proposed to define the term ''Person'' as a provider (as defined in § 400.202) or a supplier (as defined in § 400.202). We noted that this proposed definition does not include a beneficiary and that our proposal was consistent with the definition of a ''person'' in section 1128J(d)(4)(C) of the Act.

We received a number of comments regarding the definitions in proposed § 401.303.

Comment: A number of commenters expressed support for the proposed definition of ''overpayment.'' However, commenters recommended that CMS exclude routine, day-to-day business practices from the definition. Examples of practices commenters cited included: (1) Items representing refunds from the return of a product where a credit will be issued; (2) routine changes to dates of service for rental periods as patients start and stop therapy, causing a change in rental periods and account adjustments; and (3) errors in payment by a Medicare contractor that lead to an excess payment. Commenters stated that these and other types of overpayments are currently reported and returned through the claims adjustment or reversal process and the credit balance reporting process. Commenters stated that these existing processes worked well and should be recognized in the rule. Many commenters stated that CMS should consider these processes as part of the definition of ''applicable reconciliation'' in proposed § 401.305(c), which would mean any amounts refunded through the claims adjustment or reversal and credit balance reporting would not fall within the definition of ''overpayment.'' Commenters stated that amounts refunded through claims adjustment/reversal or credit balance reporting do not represent fraud, waste, or abuse, which, commenters state, CMS is seeking to curtail in this rule. Also, commenters believed that expanding the meaning of ''applicable reconciliation'' in the ''overpayment'' definition would ease the burden of compliance on providers and suppliers.

Response: We understand the commenters concerns related to the definition of overpayment. As explained in the proposed rule, our proposed definition of overpayment mirrors section 1128J(d)(4)(B) of the Act. We understand the commenters' concerns about the breadth of this definition and believe we have appropriately addressed them by expanding the ways in which overpayments may be reported and returned to include the claims adjustment or reversal and credit balance reporting process, as discussed in more detail in section II.C.4. of this final rule. This change should reduce the administrative burden issue that various commenters raised. We decline to expand ''applicable reconciliation'' beyond cost reporting for reasons discussed in greater detail later in this section.

With respect to the statements regarding fraud, waste, and abuse, we recognize that many commenters posed questions and concerns about this rule's relationship to the prevention of fraud, waste, and abuse, and the FCA. While these issues will be addressed in more detail in section II.C.1. of this final rule, we recognize that not all Medicare overpayments involve fraudulent activity (though some do). Again, overpayments are 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. These funds might be received or retained due to fraud or due to more inadvertent reasons.

Our general aim of this final rule is to strengthen program integrity and to ensure that the Medicare Trust Funds are protected and made whole and that taxpayer dollars are not wasted. An overpayment must be reported and returned regardless of the reason it happened—be it a human or system error, fraudulent behavior, or otherwise. However, as discussed in section II.C.4., the nature of the overpayment will affect a provider's or supplier's decision about the most appropriate mechanism and recipient of the overpayment report and refund.

Comment: A number of commenters requested that overpayments not caused by the provider or supplier or that were otherwise outside of the provider or supplier's control should be excluded from our proposed definition of overpayment. Examples of this situation offered by commenters included—(1) a

CMS system error classifying a Medicare beneficiary as fee-for-service when the beneficiary was enrolled in a MA Plan; or (2) if the Medicare contractor makes a duplicate payment, pays for a non-covered service due to a contractor system edit problem, or fails to implement a national or local coverage decision correctly, resulting in an erroneous payment.

Response: We disagree with the commenters that certain types of payments, including those made as a result of an error by any particular party, should be excluded from the definition of an overpayment. We do not see any basis to exclude an overpayment from the requirements of section 1128J(d) of the Act because it may not have been caused by or was otherwise outside the control of the provider or supplier. The plain language of section 1128J(d)(1) of the Act states that providers and suppliers are obligated to report and return any overpayment that they have received within the specified statutory timeframes. We do not believe it is necessary for providers or suppliers to make determinations regarding whether they were the cause of an overpayment in lieu of reporting and returning any identified overpayments as required by this rule.

Comment: A commenter requested that the overpayment example we used in the preamble regarding a patient death occurring before the service date on a submitted claim not be considered an overpayment. The commenter stated that there could be a gap between the time of the patient's exam and the interpretation of images, during which period the patient could expire. While the commenter conceded that our example of an overpayment situation relating to the relationship between the date of a beneficiary's death and the date of service would generally be true (for example, in the case of a claim for an operation or an office visit with a date of service subsequent to a beneficiary's date of death), the commenter believed there are certain circumstances where this relationship would not, by itself, be dispositive.

Response: As we stated in the preamble to the proposed rule, the examples were not intended to be an exhaustive list of overpayment situations. Nor were they intended to address all potential factual permutations and coverage rules that determine whether a particular claim is associated with an overpayment. Providers and suppliers should analyze the facts and circumstances relevant to a particular situation to determine whether an overpayment exists.

Comment: Regarding our overpayment example ''errors and non-reimbursable expenditures in cost reports,'' a commenter requested that we rephrase our example to read: ''Increases in reimbursement resulting from errors and non-reimbursable expenditures in cost reports.'' The commenter indicated that the ''increase in reimbursement'' language is more accurate.

Response: We agree that ''increases in reimbursement resulting from errors and non-reimbursable expenditures in cost reports'' is a more accurate example for purposes of this rule. Providers and suppliers need to supply accurate information on their cost report. However, this rule concerns reporting and returning overpayments received by the provider or supplier. Therefore, if the error or non-reimbursable cost at issue did not result in an increase in reimbursement, then no overpayment was received and section 1128J(d) of the Act is not implicated.

Comment: Some commenters requested that we specifically define what it means to ''over-code'' and how a determination would be made as to whether the miscoding was deliberate. For example, a commenter referenced a physician billing for an evaluation and management (E&M) code as a level III (CPT code 99213), but an auditor determines that the documentation for the visit only supports a level II service (CPT code 99212). The commenter states that it is unclear from the proposed rule whether, in this instance, the physician would be in violation of the reporting rules and liable for penalties.

Response: Over-coding, or the more commonly used term upcoding, is illustrated by the example given by the commenter. However, the commenter appears to believe that the physician only has an obligation to report and return the overpayment if the upcoding was done deliberately. To clarify, providers and suppliers must report and return overpayments identified as a result of upcoding, whether the inappropriate coding was intentional or unintentional. We discuss the steps that must be taken when a provider or supplier has identified an overpayment in section II.C. of this final rule.

Comment: A commenter requested CMS retract all of the overpayment examples in the proposed rule and republish a proposed rule including all specific examples of what CMS considers overpayments. In the alternative, the commenter objected to all of the examples except duplicate payments because, according to the commenter, these examples are inconsistent with Medicare's practice to make estimated payments for services with the knowledge that a reconciliation of those payments to actual costs will be completed at a later date when the actual costs or other relevant information become available. According to the commenter, the word ''overpayment'' implies some payment was appropriate but the actual amount of payment was over the appropriate amount. Thus, the commenter stated that the examples are inconsistent with the purpose of the statutory and regulatory definition, with industry practice, and with the general industry understanding of what an overpayment is in light of the cost report reconciliation process.

Response: We disagree with both of the commenter's suggestions. As stated earlier, the examples were illustrative and not intended as an inclusive list of all examples of overpayments. We are unable to make blanket statements or address every factual permutation in this rulemaking, and thus it is not feasible for us to enumerate all specific examples of overpayments. Providers and suppliers should analyze the facts and circumstances relevant to their situation to determine whether an overpayment exists.

In instances where interim payments are made based on estimated costs, an overpayment is not deemed to exist for purposes of this rule until an applicable reconciliation has occurred in accordance with § 401.305(c). We also disagree with the commenter's statement that Medicare's practice is to make estimated payments for services with the knowledge that a reconciliation of those payments to actual costs will be completed at a later date. While some payments are cost-based estimated payments as acknowledged in the proposed rule, many payments are not, such as claims-based payments under fee-for-service or prospective payment systems. For example, the first preamble example is a Medicare payment for non-covered services which, in most cases, would be a claims-based payment that is not an estimated payment subject to cost report reconciliation. In addition, we disagree that the term ''overpayment'' implies that some payment was appropriate. Section 1128J(d) of the Act defines overpayment to include any funds that a person receives or retains to which the person is not entitled after applicable reconciliation. In the case of a non-covered service, as well as others, the amount to which the person is entitled is zero.

Comment: Several commenters requested clarification that an

overpayment consists only of the amount of payment a provider or supplier receives in excess of funds it should have received for the services rendered. For instance, if a supplier was paid $40 for a claim when it should have received $30, the commenters questioned whether the overpayment amount is $10 and not the entire $40 amount paid.

Response: In circumstances where a paid amount exceeds the appropriate payment amount to which a provider or supplier is entitled, the overpayment is the difference between the amount that was paid and the amount that should have been paid. In addition, there are instances where payment is made for an item or service specifically not payable under the Act (for example, claims resulting from Anti-Kickback Statute or physician self-referral law violations or claims for items and services furnished by an excluded person), or where the payment was secured through fraud. In these types of situations, the overpayment typically consists of the entire amount paid.

Comment: Several commenters requested that CMS clarify in the final rule that potential overpayments only exist if a provider or supplier retains funds to which it was not entitled to at the time that it received the funds. Commenters stated that subsequent changes in law, regulation, or guidance (such as coding rules, carrier edits, and national and local coverage decisions) should not render payments that were proper at the time they were made overpayments at a later date.

Response: We agree that payments that were proper at the time the payment was made do not become overpayments at a later time due to changes in law or regulation, unless otherwise required by law. Changes in guidance or coverage policy also usually will not alter whether a prior payment should be considered an overpayment, although there can be circumstances in which guidance is issued to clarify existing law, regulation, or coverage rules that would make clear that a past payment is an overpayment. Typically, overpayments would be determined in accordance with the effective date of any changes in law, regulation, or policy. Providers and suppliers should analyze the facts and circumstances present in their situation to determine whether an overpayment exists.

Comment: Some commenters stated that the concept of ''overpayment'' is not fair in some situations. The commenters stated that certain reasons for an overpayment, such as ''insufficient documentation'' or ''lack of medical necessity'' are extremely difficult to define objectively.

Response: The definition of overpayment is fixed in statute. Sufficient documentation and medical necessity are longstanding and fundamental prerequisites to Medicare coverage and payment.

Comment: A commenter requested clarification of the meaning of ''entitled.'' The commenter stated that, once the statute of limitations has run on the government's ability to sue for breach of contract or recoupment, the provider has a vested right to the payment and is ''entitled'' to the funds. The commenter recommended that the final rule recognize that statutes of limitation, setoff, and other defenses may be considered in determining whether an overpayment exists.

Response: We believe that the statutory language clearly states that ''entitled'' means entitled under title XVIII or XIX of the Act. This final rule addresses payments under title XVIII and thus, Medicare entitlement depends upon whether the funds were received in conformance to the payment rules set forth in the Act and its implementing regulations. We do not opine on any theories for the government's pursuit of recovering overpayments, whether those theories are at law or equitable in nature. The purpose of this rule is to detail the providers and suppliers' obligations under section 1128J(d) of the Act to report and return overpayments they have received.

Comment: A number of commenters questioned the treatment of underpayments that providers and suppliers may identify in the course of identifying overpayments. Some commenters requested an explanation of the process by which providers and suppliers may recoup underpayments. Other comments proposed that providers and suppliers should be allowed to offset identified underpayments against identified overpayments when determining the repayment amount. Finally, several commenters suggested that the lookback period for overpaid claims should be the same as the lookback period for underpaid claims. Commenters suggested that we consider allowing providers and suppliers more than the currently allowed one year period to rebill a claim to correct an identified underpayment. Underpayment lookback periods of 3 years and 10 years (to match the proposed lookback period) were recommended by commenters.

Response: This final rule implements section 1128J(d) of the Act, which concerns overpayments, not underpayments. Thus, underpayment issues are outside the scope of this rulemaking. Under existing policies, providers and suppliers can seek to address underpayments by requesting reopenings under § 405.980(c).

Comment: Several commenters recommended that we ensure that refunded overpayments will be recorded and removed from the total amount paid by Medicare Part B for purposes of the sustainable growth rate formula (SGR).

Response: The Medicare Access and CHIP Reauthorization Act repealed the SGR. Overpayment refunds were recorded and removed from the total Medicare Part B expenditures for purposes of calculating the SGR, during the period for which the SGR was in effect under section 1848 of the Act.

Comment: Several commenters questioned whether providers and suppliers need to report and return Medicare secondary payer refunds under this final rule.

Response: Yes, overpayments where the provider or supplier received primary payment from both a primary payer other than Medicare and a primary payment from Medicare (''provider/supplier duplicate primary payments'') must be refunded. Overpayments where the provider/supplier failed to file a proper claim in accordance with 42 CFR 411.24(l) must also be refunded.

Comment: A commenter appreciated the clarification in the proposed rule that the statutory definition of person, for purposes of reporting and returning overpayments, does not include beneficiaries and encouraged CMS to finalize the proposed definition. Another commenter disagreed with the proposed rule's exclusion of beneficiaries from the ''person'' definition and requested an explanation for the exclusion.

Response: We appreciate the comment in support of the proposed definition and note that the proposed definition of ''person'' is in accordance with section 1128J(d)(4)(C)(ii) of the Act which excludes beneficiaries from the definition of the term ''person.''

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

Section 1128J(d) 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) contained this 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.

1. Meaning of Identified (Proposed § 401.305(a))

In proposed § 401.305(a)(2), we stated 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 stated in the preamble that we proposed this definition in part because section 1128J(d) of the Act provides that the terms ''knowing'' and ''knowingly'' have the meaning given those terms in the FCA (31 U.S.C. 3729(b)(1)). While the statutory text does not use these terms other than in the definitions, we believed the Congress' use of the term ''knowing'' in the Affordable Care Act was intended to apply to determining when a provider or supplier has identified an overpayment. We also stated that 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 research.

We also noted in the February 2012 proposed rule (77 FR 9182) that, in some cases, a provider or supplier may receive information concerning a potential overpayment that creates a duty to make a reasonable inquiry to determine whether an overpayment exists. If the reasonable inquiry reveals an overpayment, the provider or supplier 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 or supplier 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 may have incurred a duty to timely investigate that matter, depending on whether the hotline complaint qualifies as credible information of a potential overpayment. Whether the complaint qualifies as credible information is a factual determination. If the provider incurs a duty and 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 obligation under the proposed rule. However, if 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 provided the following examples, which were intended to be illustrative and not an exhaustive list of circumstances:

- 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 a duty 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. However, 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.)

Finally, we also discussed in the proposed rule (77 FR 9183) issues associated with 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 FCA. In the proposed rule, we recognized 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 stated that we believe that providers and suppliers 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; therefore would have no duty to report or 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, we proposed that the provider or supplier 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.

Comment: Several commenters noted that section 1128J(d) of the Act has two separate provisions addressing overpayments and questioned whether the proposed rule conflated those provisions. Section 1128J(d)(1) of the Act creates the threshold obligation that if a person has received an overpayment, the person shall report and return the overpayment. Once that threshold obligation is triggered—receipt of the overpayment—then section 1128J(d)(2) of the Act addresses the timing of fulfilling the obligation to report and return, either the later of the date which is 60 days after the date on which the overpayment was identified or the date any corresponding cost report is due, if applicable. Commenters noted that the proposed rule may conflate these two, separate obligations in proposed 42 CFR 401.305(a)(1), which stated that 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 42 CFR 401.305. Commenters stated that this proposed rule language tied the threshold obligation to identifying the overpayment and not to receiving the overpayment.

Response: We agree with the commenters and have amended § 401.305(a)(1) to separate these two concepts. Section 1128J(d)(1) of the Act plainly mandates that any overpayment received by a person shall be reported and returned. We interpret this language as showing the Congress intended to more clearly codify providers and suppliers' existing duty to return overpayments they have received, which would necessarily include taking appropriate actions to determine whether the provider or supplier has in fact received an overpayment. The ''receipt'' threshold obligation is consistent with both the initial standard for identification in the proposed rule and the standard for identification in this final rule. We do not believe the Congress intended to create a loophole to the threshold ''receipt'' obligation through the timing provision for fulfilling this obligation. Limiting the standard for identification to actual knowledge would create that loophole and would conflict with the plain statutory mandate to report and return any overpayments the person has received. In addition, we believe we have the responsibility under the Secretary's rulemaking authority to interpret the statute in an appropriate manner to create safeguards that protect the integrity of its plain mandate—to report and return overpayments the person has received.

Comment: Several commenters agreed with the proposed rule's definition of identification. Commenters stated that the proposed rule provides appropriate incentives for providers and suppliers to pay attention to red flags indicating a potential overpayment may have been received. These commenters believe providers and suppliers should be encouraged to proceed with diligence to investigate information suggesting an overpayment, to report, and take corrective actions, and adopt ''best practices'' to prevent overpayments. A commenter stated that adoption of this actual and constructive knowledge standard will promote consistency and will allow government and providers and suppliers to base their conduct and positions on case law interpreting those terms. Another commenter acknowledged the need for the reckless disregard/deliberate ignorance standard to deter evasive conduct and fraudulent concealment. However, the commenter requested that CMS further clarify this standard.

Response: We appreciate the comments and agree with the commenters' interpretation of the proposed rule. We continue to believe that the proposed standard is an appropriate interpretation of section 1128J(d) of the Act within the Secretary's rulemaking authority. As explained in this final rule, we have adjusted the standard for identification after careful consideration of the numerous comments submitted. We believe that the final rule strikes the right balance between creating a flexible yet strong standard that applies to many different circumstances.

Comment: Many commenters objected to the proposed inclusion of reckless disregard and deliberate ignorance in the standard for identification. These commenters claimed that there is no statutory basis to apply a standard beyond actual knowledge to the term ''identified.'' Specifically, commenters disagreed with our statement in the preamble that the Congress' use of the term ''knowing and knowingly'' in section 1128J(d)(4)(A) of the Act indicates the Congress' intent to apply a constructive knowledge standard to ''identified.'' Commenters noted that these terms are not used elsewhere in section 1128J(d) of the Act except the definition section. Commenters attributed section 1128J(d)(4)(A) of the Act as a drafting error based on the House version of the Affordable Care Act, H.R. 3962, which used the term ''knows.'' According to commenters, the replacement of the word ''knows'' with ''identified'' in the final version of the Affordable Care Act is indicative of Congressional intent not to equate the FCA knowledge standard to ''identified.'' The commenters argue that had the Congress intended to apply the statute this expansively, it would have drafted the provision to extend liability to those who fail to report and return an overpayment within 60 days of the date on which the overpayment was identified or should have been identified.

Response: We disagree with the commenters' arguments. While we acknowledge that the terms ''knowing'' and ''knowingly'' are defined but not otherwise used in section 1128J(d) of the Act, we believe that the Congress intended for section 1128J(d) of the Act to apply broadly. If the requirement to report and return overpayments only applied to situations where providers or suppliers had actual knowledge of the existence of an overpayment, then these entities could easily avoid returning improperly received payments and the purpose of the section would be defeated.

Comment: Several commenters suggested applying the ''knowing'' concept to ''retained'' instead of our proposed approach. Commenters believed that applying the constructive knowledge standard to trigger the enforcement provisions would be more appropriate than our proposal.

Response: We considered applying a constructive knowledge standard to the term ''retained'' and determined that our approach was both a better reading of the law and a better approach to protecting the program. As discussed previously, we believe there is a strong statutory basis for our rule. Also, modifying ''retained'' does not eliminate the programmatic concern of the ''ostrich defense''—that the plain mandate to report and return overpayments received would be avoided by not taking action to obtain actual knowledge of an overpayment. The enforcement provision at section 1128J(d)(3) of the Act depends on the person retaining the overpayment after the deadline for reporting and returning. If the deadline never passes because the person avoids obtaining actual knowledge of the overpayment, then the enforcement provision is rendered toothless.

Comment: Commenters also expressed concern that ''reckless disregard'' and ''deliberate ignorance'', as used in proposed § 401.305(a)(2), are

ambiguous terms that do not adequately inform providers and suppliers of the circumstances that would give rise to a duty to investigate and fail to provide sufficient guidance as to what efforts are necessary to avoid overpayment liability. Some commenters stated that the proposed rule actually provides a disincentive to undertake compliance audits for fear of creating liability for identifying an overpayment.

Response: We appreciate the comments and have revised the regulatory provision in the final rule by removing the terms ''actual knowledge'', ''reckless disregard'', and ''deliberate ignorance''. The final rule states that a person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. A person should have determined that the person received an overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment. ''Reasonable diligence'' includes both proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments and investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining credible information of a potential overpayment.

The regulation uses a single term—reasonable diligence—to cover both proactive compliance activities to monitor claims and reactive investigative activities undertaken in response to receiving credible information about a potential overpayment. We believe that compliance with the statutory obligation to report and return received overpayments requires both proactive and reactive activities. In addition, we also clarify that the quantification of the amount of the overpayment may be determined using statistical sampling, extrapolation methodologies, and other methodologies as appropriate.

As to the circumstances that give rise to a duty to exercise reasonable diligence, we are not able to identify all factual scenarios in this rulemaking. Providers and suppliers are responsible for ensuring their Medicare claims are accurate and proper and are encouraged to have effective compliance programs as a way to avoid receiving or retaining overpayments. Indeed, many commenters told us that they have active compliance programs and that we should recognize these compliance efforts in the final rule. It was also apparent from some commenters that they do not currently engage in compliance efforts to ensure that the claims they submitted to Medicare were accurate and proper and that payments received are appropriate. We advise those providers and suppliers to undertake such efforts to ensure they fulfill their obligations under section 1128J(d) of the Act. We believe that undertaking no or minimal compliance activities to monitor the accuracy and appropriateness of a provider or supplier's Medicare claims would expose a provider or supplier to liability under the identified standard articulated in this rule based on the failure to exercise reasonable diligence if the provider or supplier received an overpayment. We also recognize that compliance programs are not uniform in size and scope and that compliance activities in a smaller setting, such as a solo practitioner's office, may look very different than those in larger setting, such as a multi-specialty group. Compliance activities may also appropriately vary based on the type of provider.

We note that in discussing the standard term ''reasonable diligence'' in the preamble, we are interpreting the obligation to ''report and return the overpayment'' that is contained in section 1128J(d) of the Social Security Act. We are not seeking to interpret the terms ''knowing'' and ''knowingly'', which are defined in the Civil False Claims Act and have been interpreted by a body of False Claims Act case law.

Comment: Several commenters stated that they interpreted the preamble to the proposed rule as permitting providers and suppliers time to conduct a reasonable inquiry before the 60-day time period begins to run. These commenters noted that the preamble provides that providers and suppliers may receive information concerning a potential overpayment that creates a duty to conduct a reasonable inquiry to determine whether an overpayment exists. If the reasonable inquiry reveals an overpayment, then the provider 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 or supplier knowingly retaining an overpayment because it acted in reckless disregard or deliberate ignorance of whether it received such an overpayment. Commenters stated that this explanation and the examples in the preamble together suggested that once a provider is placed on notice of a potential overpayment, it must conduct a reasonably diligent inquiry under the circumstances and the 60-day period does not start until either the inquiry reveals an overpayment or the provider or supplier is reckless or deliberately ignorant because it failed to conduct the reasonable inquiry. Commenters requested that we clarify whether this interpretation was accurate.

Response: We agree with the commenters' interpretation of the proposed rule and have revised § 401.305(a) and (b) in this final rule to clarify the duty to investigate through a reasonable diligence standard. When a person obtains credible information concerning a potential overpayment, the person needs to undertake reasonable diligence to determine whether an overpayment has been received and to quantify the amount. The 60-day time period begins when either the reasonable diligence is completed or on the day the person received credible information of a potential overpayment if the person failed to conduct reasonable diligence and the person in fact received an overpayment.

Comment: Commenters questioned how quantification of the overpayment fit into the proposed rule. Specifically, commenters stated that the proposed rule did not expressly address the difference between determining that an overpayment has been received and the auditing work necessary to calculate the overpayment amount. Commenters stated that the calculation necessarily must happen before the overpayment can be reported and returned.

Response: We agree and have revised the language in § 401.305(a)(2) to clarify that part of identification is quantifying the amount, which requires a reasonably diligent investigation.

Comment: Commenters expressed concern over whether the proposed rule treats failing to conduct a ''reasonable inquiry'' with ''all deliberate speed'' as a violation of section 1128J(d) of the Act by itself. In other words, commenters questioned whether the mere possibility of an overpayment, without there actually being an overpayment, can establish liability at any point.

Response: We understand the commenters' concerns and have amended the language accordingly. The final rule clarifies that failure to conduct reasonable diligence does not by itself create liability under section 1128J(d) of the Act. The statutory obligation is to report and return received overpayments; thus a provider or supplier must also have received an overpayment that it should have identified before liability can exist under section 1128J(d) of the Act.

Comment: Several commenters requested clarity on the phrase ''reasonable inquiry.'' Some commenters suggested defining ''reasonable inquiry'' as a good faith investigation that is promptly conducted until its conclusion by persons with sufficient knowledge and experience to make such determination.

Response: We appreciate the commenters' suggestions and amended the final rule as described in this section by creating a ''reasonable diligence'' standard in § 401.305(a)(2). We also appreciate the commenters' suggested definition and incorporated various suggestions into our discussion of what constitutes ''reasonable diligence,'' as explained previously in this section. We also note that although the preamble to the proposed rule used both ''reasonable diligence'' and ''reasonable inquiry,'' for clarity, we used only the term ''reasonable diligence'' in this final rule.

Comment: Commenters suggested that we provide more detail on how to judge what is ''reasonable'' about a reasonable inquiry, such as taking into account the unique characteristics of the provider or supplier and the nature of the problem. Accordingly, commenters suggested defining ''reasonable inquiry'' as ''reasonably diligent under the circumstances, taking into account the size, capacity, workload, technological sophistication, and resources of the subject provider or supplier and the complexity, uniqueness, and significance of the suspected overpayment at issue.'' In addition, commenters recommended that we provide a list of illustrative hallmarks of a reasonable inquiry, but also stated that some of these hallmarks will be fact-dependent.

Response: We appreciate the comments and believe we have provided additional explanation of the meaning of ''reasonable diligence'' in this final rule. However, we decline to expressly adopt the commenters' proposed definitions and suggestions. We believe that the concept of ''reasonableness'' is fact-dependent.

Comment: A number of commenters requested clarification on the meaning of ''all deliberate speed'' a phrase used in the preamble to the proposed rule. Commenters stated that we effectively established a time limit for preliminary action before the 60-day clock began to toll, yet did not clearly state what this time limit is or what a person must do to meet it. Commenters stated that the proposed rule was not clear about how to determine whether an ongoing investigation occurred with ''all deliberate speed.'' Commenters noted that in many circumstances, multiple people will be involved in determining whether an overpayment exists and in what amount, such as auditors, billing personnel, and legal counsel. Commenters believed we should issue additional guidance in the final rule, particularly what documentation we expect providers and suppliers to maintain to show compliance with the rule. Some commenters suggested that we adopt an approach that would allow for a ''reasonable period of time to investigate'' a potential overpayment. Other commenters pointed to the Federal Acquisitions Regulations (FAR) treatment of the time between first learning of an allegation and the requirement to disclose credible evidence of an overpayment. The commenters noted that the FAR drafters considered but rejected adding a set period of time, such as 30 days, to the disclosure requirement. (See the November 12, 2008 final rule (73 FR 67074).) Under FAR, failure to timely disclose credible evidence of significant overpayment is measured from the date of the determination by the contractor that the evidence is credible. (See the November 12, 2008 final rule (73 FR 67075).) A few commenters requested additional time to conduct the inquiry in the event of an emergency, such as a natural disaster affecting the provider or supplier.

Response: The preamble to this final rule does not include the phrase ''all deliberate speed'' as the benchmark of compliance. Instead, we adopt the standard of reasonable diligence and establish that this is demonstrated through the timely, good faith investigation of credible information, which is at most 6 months from receipt of the credible information, except in extraordinary circumstances. We considered but rejected adopting a ''reasonable period of time to investigate'' standard because we concluded that an open-ended timeframe would likely be viewed as no more clear than ''all deliberate speed'' and establishing a time frame would better respond to commenters' concerns on this issue. We choose 6 months as the benchmark for timely investigation because we believe that providers and suppliers should prioritize these investigations and also to recognize that completing these investigations may require the devotion of resources and time. Receiving overpayments from Medicare is sufficiently important that providers and suppliers should devote appropriate attention to resolving these matters. A total of 8 months (6 months for timely investigation and 2 months for reporting and returning) is a reasonable amount of time, absent extraordinary circumstances affecting the provider, supplier, or their community. What constitutes extraordinary circumstances is a fact-specific question. Extraordinary circumstances may include unusually complex investigations that the provider or supplier reasonably anticipates will require more than six months to investigate, such as physician self-referral law violations that are referred to the CMS Voluntary Self-Referral Disclosure Protocol (SRDP). Specific examples of other types of extraordinary circumstances include natural disasters or a state of emergency.

As for documentation, it is certainly advisable for providers and suppliers to maintain records that accurately document their reasonable diligence efforts to be able to demonstrate their compliance with the rule.

Comment: Several commenters recommended that CMS define identification as actual knowledge of credible evidence that an overpayment has occurred and of the actual amount received in excess of what was due. Commenters stated that ''credible evidence'' is a well-understood concept; that is, information that, considering its source and the circumstances, supports a reasonable belief that there has been an overpayment. The credible evidence standard differs from a credible ''allegation'' because, according to commenters, it requires some level of diligence to determine whether the information is credible.

Response: We appreciate the comments but decline to adopt this definition of ''identification.'' It limits the obligation to instances in which the provider or supplier has actual knowledge, which, as discussed previously, we do not believe is consistent with section 1128J(d) of the Act. As discussed previously, we have clarified that providers and suppliers may conduct a timely investigation of credible information before the 60-day deadline is triggered. We also decline to adopt a ''credible evidence'' standard because we are concerned there may be further confusion about the term ''evidence'' because of its significance in the litigation context. Instead, as noted previously, we have adopted a ''credible information'' standard. We believe credible information includes information that supports a reasonable belief that an overpayment may have been received. This standard should address commenters' concern of being required to investigate every instance or complaint concerning a potential overpayment. We recognize that providers and suppliers may receive

information that could be considered not credible. Determining whether information is sufficiently credible to merit an investigation is a fact-specific determination.

Comment: Several commenters suggested an alternative definition to identification as ''when, after the person receives reliable evidence (as defined at 42 CFR 405.902) that it has received an overpayment and, through the exercise of reasonable diligence has determined that an overpayment exists, the person has quantified the amount of the overpayment within a reasonable degree of certainty.'' Commenters stated that such a standard would provide some degree of comfort that providers and suppliers would not be under a duty to investigate every ''whiff'' of an overpayment and removes the constructive knowledge standard. Commenters also stated this definition would acknowledge that an overpayment cannot be reported and returned if it is not quantified, as well as the circumstances, such as when statistical sampling and extrapolation are used, when it may not be possible to know with 100 percent accuracy the exact amount of an overpayment. These commenters stated that it also acknowledges that in some circumstances providers and suppliers may need more time to commence an inquiry. Other commenters suggested a similar alternative ''when the person has actual knowledge of an overpayment and is able to quantify the overpayment with reasonable certainty, or when a person does not initiate an inquiry within a reasonable amount of time after receiving credible information suggesting the existence of a potential overpayment.''

Response: We appreciate the comments and incorporated some of these ideas into the final rule. We agree that statistical sampling and extrapolation are an appropriate component of a provider's reasonable diligence in investigating an overpayment and can serve as an appropriate way to calculate an overpayment amount. The final rule provides guidance for reporting overpayments identified through such statistical methods. We also use the term ''credible information'' in the preamble as suggested in these comments. We considered but declined to adopt the term ''reliable evidence'' as defined at 42 CFR 405.902 because it is potentially too limited and the term ''evidence'' is prone to confusion as ''credible evidence'' discussed previously. Finally, we also disagree with the commenters' proposals to the extent they suggest identification efforts are limited to reactive investigations (and do not include the proactive compliance activities necessary to monitor for receipt of overpayments) or actual knowledge (and do not include the constructive knowledge standard discussed previously).

Comment: Commenters stated that the 60-day time period should start to run on the day that an overpayment inquiry has concluded, confirmed that there has been an overpayment, and produced sufficient information to calculate the precise overpayment amount. Commenters stated that this standard would avoid confusion about when to report.

Response: We recognize that additional clarity was necessary and revised the final rule to clarify that the 60-day time period starts to run when the overpayment has been identified based on the standard for identified in § 401.305(a)(2). These commenters do not appear to take into account statistical sampling and extrapolation calculations, which is something other commenters suggested that we recognize. As discussed previously, we also interpret section 1128J(d) of the Act to include both an actual knowledge and a constructive knowledge standard.

Comment: Commenters questioned how we proposed determining the actual date for triggering the 60-day reporting and returning deadline and for when a person acts in reckless disregard or deliberate ignorance of an overpayment. Commenters suggested that we provide clear guidance as to what actions a provider or supplier must take to avoid a determination that it is in reckless disregard or deliberate ignorance of the existence of an overpayment.

Response: We believe the final rule provides additional clarity on how we revised the constructive knowledge standard for when a person has identified an overpayment. The 60-day time period begins either when the reasonable diligence is completed and the overpayment is identified or on the day the person received credible information of a potential overpayment if the person fails to conduct reasonable diligence and the person in fact received an overpayment. This standard, as well as the requirement to conduct a timely, good faith investigation in response to obtaining credible information of a potential overpayment, provide ''bright line'' standards that should assist providers and suppliers in structuring their compliance programs to comply with the rule.

Comment: Several commenters questioned whether, after finding a single overpaid claim, it is appropriate to inquire further to determine whether there are more overpayments on the same issue before reporting and returning the single overpaid claim. Expanding the inquiry may take additional time and, according to commenters, it is unclear whether the 60-day time period has begun to run for the single overpaid claim. Similarly, several commenters also questioned whether compliance with the rule required periodic repayments while the person is conducting the review. For example, commenters noted that a provider or supplier may conduct a probe sample of claims and discover a possible overpayment with respect to some of the claims. Commenters questioned whether in this situation the provider or supplier has identified an overpayment that would require reporting and returning the overpayment for the probe sample claims, even though the probe sample review is typically one step in the usual audit process. According to commenters, validation of the probe sample findings would then lead to expanding the audit beyond the probe sample and conducting a root cause analysis to determine the cause of the overpayment and whether more overpayments exist. Commenters stated that it is a common practice to include the probe sample in the expanded audit to extrapolate an error rate to the entire population. Commenters stated that permitting this practice would result in a more robust analysis of the overpayment and a more accurate repayment to the government. The premature return of any overpayment identified during the probe sample audit could taint the results of the complete review, according to commenters.

Response: We understand the commenters' concerns and believe that the final rule's clarifications should address these concerns. We expect providers and suppliers to exercise reasonable diligence and to quantify, report, and return the entire overpayment in good faith. Part of conducting reasonable diligence is conducting an appropriate audit to determine if an overpayment exists and to quantify it. Providers and suppliers are obligated to conduct audits that accurately quantify the overpayment. After finding a single overpaid claim, we believe it is appropriate to inquire further to determine whether there are more overpayments on the same issue before reporting and returning the single overpaid claim. To the extent this concern is based on a question about when the 60-day clock begins to run, the final rule clarifies that identification

occurs once the person has or should have through the exercise of reasonable diligence, determined that the person received an overpayment and quantified the amount of the overpayment.

We understand that a common way to conduct an audit is to use a probe sample and then incorporate that probe sample into a larger full sample as the basis for determining an extrapolated overpayment amount. In the probe sample, it is not appropriate for a provider or supplier to only return a subset of claims identified as overpayments and not extrapolate the full amount of the overpayment. We believe that in most cases, the extrapolation can be done in a timely manner consistent with the identification requirements of this rule and that the provider or supplier should not report and return overpayments on specific claims from the probe sample until the full overpayment is identified.

Comment: Some commenters requested clarification that a provider or supplier with an active and robust compliance program that contains the elements suggested by OIG's compliance program guidance and the Federal Sentencing Guidelines cannot be found to have acted with ''reckless disregard or deliberate ignorance'' with respect to overpayments. Some commenters suggested that a provider that has a ''certified'' or ''approved'' compliance program should be entitled to a presumption that any overpayments are simple mistakes rather than fraud or abuse.

Response: We disagree with the commenters. Based on our experience, it is possible for providers or suppliers who have active compliance programs to commit fraud. Moreover, even if an overpayment is the result of a mistake, rather than fraud or abuse, the provider or supplier has an obligation to report and return it under section 1128J(d) of the Act.

Comment: Commenters expressed concerns that the proposed rule's constructive knowledge standard for ''identified'' introduces a subjective standard that would lead to the 60-day clock beginning to run on a date that a person ''should have known'' about an overpayment, although it actually had no knowledge at all. For example, if a health care entity accidentally programs its computers incorrectly, and as a result, erroneously bills and is paid for a service, commenters questioned whether the addition of the ''reckless disregard'' standard suggests that one could argue that the company should have been aware of the error, and therefore is liable for a false claim, even if the company has a robust compliance program that fails to uncover the error. Commenters believe that the proposed definition of ''identified'' raises the possibility that CMS, other regulators, or qui tam relators may second-guess the provider and question whether the provider exercised ''reasonable diligence'' and made a ''reasonable inquiry'' ''with all deliberate speed'' in assessing when an overpayment should have been identified.

Response: We understand commenters' concerns and believe the changes made to the proposed rule in this final rule should provide additional clarity for providers and suppliers on the actions they need to take to comply with the rule. With regard to the commenters concern that as a result of this final rule CMS, other regulators, or qui tam relators may second-guess the provider and question whether the provider exercised ''reasonable diligence'' and made a ''reasonable inquiry'' ''with all deliberate speed,'' we note that it has long been true that many activities in the provision of health care, including billing the Medicare program, are subject to review by various stakeholders. This rule does not change that situation or significantly expand the areas that have long been subject to such review.

Comment: Several commenters expressed concerns with our statement in the preamble that we defined ''identification'' as an incentive to exercise reasonable diligence to determine whether an overpayment exists and that 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. Commenters believed this statement appeared to disregard the compliance activities of many in the health care industry and indicated that CMS did not believe providers and suppliers would engage in compliance activities without increased liability. The commenters recognized the legitimate need for this rule to not permit avoiding the report and return obligation when there is some indication of a potential overpayment simply by avoiding additional investigatory work to obtain actual knowledge. Commenters stated that voluntary compliance programs already follow this basic duty to investigate and recommended a parallel, narrowly drawn duty to investigate when there is credible evidence of the existence of an overpayment. According to commenters, this standard could apply to a variety of fact patterns, including, compliance hotline communications, internal statistical analyses identifying potential payment discrepancies, and issues raised by staff. Commenters believed this approach would satisfy our stated concern, while imposing a more reasonable administrative burden.

Response: We appreciate the commenters' concerns but decline to limit the constructive knowledge standard in the final rule to receipt of information as discussed previously. We note that certain types of information noted by commenters, such as internal statistical analyses, require some proactive action on the part of the provider or supplier to obtain that information. We are concerned that limiting the standard for identified to instances in which the provider or supplier is simply receiving information may create a disincentive for providers and suppliers to undertake those important proactive compliance activities to ensure they have properly received Medicare payments. We understand that many providers and suppliers have active compliance programs that do both proactive and reactive reviews of Medicare billing. Our intention is to capture both of those activities in this final rule.

Comment: Several commenters requested that CMS clarify that there is no duty to proactively search for overpayments without a reason to believe that a specific overpayment exists. These commenters stated that the preamble language suggests that providers and suppliers have a perpetual duty to research whether any overpayment may exist, which would be overly burdensome and not consistent with the requirements of section 1128J(d) of the Act. A commenter stated that the compliance program regulations implementing section 6401 of the Affordable Care Act may be a more appropriate mechanism for CMS to propose these requirements.

Response: These comments underscore our concern expressed in the proposed rule that some providers and suppliers might avoid performing activities to determine whether an overpayment exists. As discussed earlier, section 1128J(d) of the Act requires a person to report and return overpayments they have received. Thus, providers and suppliers have a clear duty to undertake proactive activities to determine if they have received an overpayment or risk potential liability for retaining such overpayment.

Comment: Some commenters objected to the example of an identified overpayment concerning a provider learning of services provided by an unlicensed or excluded individual. The commenter believed that such a

scenario does not automatically imply that an overpayment has occurred, but that an investigation must be conducted to determine if there is a regulatory or legal nexus between the individual's licensure or exclusion and the reimbursement.

Response: We understand the commenters' belief that the example given doesn't automatically imply than an overpayment has occurred. Billing for items or services furnished by an unlicensed or excluded person can result in receiving an overpayment. Part of determining whether an overpayment has been received in this situation is investigating the relevant facts about the activities of the unlicensed or excluded individual and reviewing the relevant laws, regulations, and billing rules.

Comment: A commenter suggested adding to the list of examples where no reasonable inquiry occurred after learning that the profits from a practice or physician were unusually high in relation to hours worked or the relative value units associated with the work.

Response: We agree that this situation could constitute credible information that would require a provider or supplier to conduct reasonable diligence. As we stated earlier, the list of examples is illustrative only and not a comprehensive list. We are unable to address all possible factual permutations in this rulemaking.

Comment: Several commenters questioned how a hotline complaint could create a duty to conduct a reasonable inquiry. A hotline complaint is made by employees or other sources and is typically used to raise allegations of improper conduct or something that may need to be investigated.

Response: Hotline complaints received by a provider or supplier may qualify as credible information of a potential overpayment under this rule, which would require the provider or supplier to exercise reasonable diligence to determine if an overpayment has occurred. Whether a hotline complaint qualifies as credible information is a factual determination. For example, receiving repeated hotline complaints about the same or similar issues may lead a reasonable person to conclude that they have received credible information that obligates conducting reasonable diligence. However, one hotline complaint may be detailed enough to lead a reasonable person to the same conclusion.

Comment: Several commenters questioned to whom within an organization CMS would attribute knowledge of the overpayment. Commenters suggested that CMS clarify that it must be a senior official who has confirmed the overpayment before ''knowledge'' can be attributed to the organization.

Response: We disagree with the commenters. As a general matter, organizations are responsible for the activities of their employees and agents at all levels.

Comment: Some commenters requested confirmation that a valid report of an overpayment bars any substantive liability under the FCA qui tam provisions. Commenters suggested that the reporting of the overpayment should result in a ''public disclosure.'' Other commenters requested clarification on the proposed rule's interaction with reverse FCA liability. Commenters suggested that a failure to report and return an identified overpayment should not lead to reverse FCA liability, unless the provider ''knowingly concealed'' or ''knowingly and improperly avoided'' the obligation. Other commenters stated that the proposed rule inappropriately applies the FCA, specifically the ''reverse false claims'' cause of action, to honest mistakes or inadvertent overpayments.

Response: We are interpreting section 1128J(d) of the Act in this rulemaking, not the FCA. In this rule, our discussion of the FCA is limited to its explicit inclusion in the enforcement provision under section 1128J(d) of the Act, which states that any overpayment retained by a person after the deadline for reporting and returning the overpayment under this rule is an obligation for purposes of the FCA.

Comment: Several commenters requested clarification about the level of resources a small provider or supplier is expected to devote to investigating potential overpayments in order to avoid being liable based on a theory of ''reckless disregard'' or ''deliberate ignorance.'' Some commenters expressed concern that resources might be diverted from patient care in order to ensure compliance with this rule. Commenters requested that CMS provide compliance guidance on how to develop compliance plans and conduct self-audits for small providers and suppliers and recommended that this guidance be coordinated with the rulemaking related to sections 6102 and 6401 of the Affordable Care Act.

Response: We understand the concern of smaller providers and suppliers. However, we are unable to provide specific guidance on resource levels or other measures to ensure compliance with this rule. Providers and suppliers, large and small, have a duty to ensure their claims to Medicare are accurate and appropriate and to report and return overpayments they have received. We have produced a number of educational materials, including the Medicare Learning Network®, which are available on our Web site, *http://www.cms.gov*.[2] OIG has also produced a number of compliance educational materials that are available on its Web site, *http://www.oig.hhs.gov*.[3]

Comment: A commenter acknowledged that while a significant increase in Medicare revenue could be an example of an identified overpayment for some types of providers, it might be inapplicable to other types of providers. Specifically, the commenter explained that laboratories are not in a position to determine the medical necessity of the services they provide because they do not order the tests. The commenter suggested that the final rule clarify that laboratories and other providers that do not directly order tests or services be exempt from any requirement to proactively conduct an inquiry into whether an overpayment exists based on the volume of Medicare work it conducts.

Response: We disagree with the commenter. All providers and suppliers have a duty to ensure that the claims they submit to Medicare are accurate and appropriate. There may be situations where a significant increase in Medicare revenue should lead a laboratory to conduct reasonable diligence.

Comment: A commenter expressed concern regarding the proposed rule's effect on hospitalists. The commenter explained that hospitalists have very little contact with the payment process because they are employed by a hospital or physician group and typically assign their Medicare payments to their employer.

Response: For purposes of this rule, an entity to which a provider or supplier has reassigned Medicare payments has a duty to determine whether it has received overpayments associated with that provider or supplier. Additionally, although the entity to which payments were reassigned has a duty to determine if it has received any overpayments, this does not mean that the individual who has reassigned his or her payments might not, in certain circumstances, also be responsible for the overpayment. This will be a fact-specific determination regarding the individual's

[2] A current, more direct link: *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNGenInfo/index.html?redirect=/mlngeninfo*.

[3] A current, more direct link: *http://oig.hhs.gov/compliance/*.

knowledge of the circumstances leading to the overpayment.

Comment: Several commenters stated that the proposed rule is inconsistent with the limitation on liability provision in section 1879 of the Act (42 U.S.C. 1395pp), in situations where the provider did not know and could not reasonably have been expected to know that the payment would not be made.

Response: We disagree with the commenters. Determinations by the Secretary with respect to liability for non-covered items or services under section 1879 of the Act are independent from the obligations of providers and suppliers under section 1128J(d) of the Act to report and return overpayments received by a provider or supplier. Section 1879 determinations are decisions by CMS about whether to make payment not withstanding certain other provisions in Title XVIII and assignment of financial responsibility for denied items or services when payment may not be made. When CMS has made such a determination that payment must be made for certain denied items or services, the resulting payment would not be an overpayment under section 1128J(d) of the Act. Moreover, determinations in accordance with section 1879 of the Act are CMS determinations; section 1879 of the Act is not applicable to the provider's or supplier's own assessment of whether funds are an overpayment. We believe it is inappropriate for providers or suppliers to make determinations regarding their own knowledge of non-coverage or whether they were the cause of an overpayment in lieu of reporting and returning an identified overpayment as required by this rule.

Comment: A number of commenters suggested including the reasonable inquiry issues in the regulatory text for clarity. Commenters noted that these issues were only discussed in the preamble and not noted in the regulatory text.

Response: We have included the reasonable diligence language in the regulatory text at § 401.305(a)(2).

Comment: Several commenters requested clarification as to how the regulations will apply to providers or suppliers who receive a possible overpayment as the result of a scheme that violates the Anti-Kickback Statute and the provider or supplier was not a party to the scheme. Commenters stated that providers or suppliers receiving a payment with no knowledge of a kickback arrangement should not be held responsible for identifying and returning the resulting overpayment. Commenters also stated that there should be no affirmative duty on innocent providers and suppliers to report a suspicion of a kickback arrangement. A commenter proposed that ''sufficient knowledge'' of a kickback should mean ''actual knowledge of the existence of the kickback or acts in reckless disregard or deliberate ignorance of the kickback.'' Additionally, some commenters suggested that the government has no right to recover ''tainted'' claims made to an innocent party that were the result of a kickback arrangement and that no overpayment exists if the provider is without fault. Comments also requested further explanation of the extraordinary situations in which the government would seek recovery from an innocent provider.

Response: As stated in the proposed rule and elsewhere in this final rule, providers and suppliers who are not a party to a kickback arrangement are unlikely in most instances to have ''identified'' an overpayment that has resulted from the kickback arrangement and would therefore have no duty to report or return it. To the extent that a provider or supplier who has received an overpayment resulting from a kickback arrangement and is not a party to a kickback arrangement but has sufficient knowledge of the arrangement to have identified the resulting overpayment, the provider or supplier must report the overpayment to CMS. However, we decline to adopt the suggested definition of ''sufficient knowledge.'' It is possible that a provider or supplier may obtain information that indicates that an arrangement may violate the Anti-Kickback Statute.

We would refer the reported overpayment and potential kickback arrangement 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). 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 extraordinary circumstances. As these issues are fact-specific, we are unable to speculate as to what facts would need to be present to qualify as extraordinary circumstances.

Comment: A commenter suggested creating additional exceptions for reporting and returning overpayments for other ''innocent provider'' situations for errors made by a third party billing company or overpayments resulting from the provider or supplier being a victim of identity theft.

Response: Providers and suppliers are responsible for the actions of their agents, including third-party billing companies. We understand that providers and suppliers are concerned that they may become victims of identity theft. Providers and suppliers should report any identity theft to law enforcement and CMS and should wait for instructions from CMS concerning returning the overpayment.

Comment: Several commenters requested clarification on the overpayment example concerning receiving a significant increase in Medicare revenue for no apparent reason and failing to make reasonable inquiry. Commenters requested guidance on what is significant. Some commenters requested that a ''significant increase'' in Medicare revenue be defined as a 25 percent increase in Medicare revenue or alternatively, allow a neutral third-party to decide when there is a ''significant increase.''

Response: We decline to adopt the commenters' suggestions and will not define the term ''significant increase.'' As stated earlier, we are unable to make blanket statements or address every factual permutation in this rulemaking. Providers and suppliers should analyze the facts and circumstances present in their situation to determine whether they have credible information that a potential overpayment exists. As discussed earlier in this section, providers and suppliers are required to exercise reasonable diligence to determine whether they have received an overpayment when there is credible information of a potential overpayment.

Comment: Commenters raised concerns about the potential for a provider or supplier to refund overpayments and that those refunded claims may become the subject of an audit by a Medicare contractor, such as a Medicare Recovery Contractor, or the OIG in the future. A commenter requested that CMS clarify that Medicare contractors should take appropriate steps to remove any claims that are the subject of an overpayment refund from the claims data warehouse so that the claims are not later subject to contractor or OIG review and recoupment for similar issues.

Response: We understand the commenters' concerns and believe that our adjustments to the process for reporting and returning overpayments discussed in section II.C.4. of this final rule address those concerns. If providers and suppliers report and return overpayments for specific claims, then

the MAC can adjust those claims. If providers and suppliers report and return using statistical sampling and extrapolation, then it is only possible to adjust the specific erroneous claims found in the sample. In this situation, providers and suppliers should retain their audit and refund documentation in the event that a Medicare contractor or the OIG audits claims that the provider or supplier believes have been previously refunded. While we will not recover an overpayment twice, we do not intend to exempt from subsequent audit by CMS, a CMS contractor or the OIG any claims that form the basis for a returned overpayment.

Comment: Some commenters stated that CMS should clarify that the obligation to report and return overpayments begins at the conclusion of a contractor or government audit, after the provider is presented with results.

Response: This rule addresses the relevant person's responsibility to report and return overpayments it has received and identified based on its own proactive analysis or any other means of identification. There are many ways, other than a government audit, that a person can identify an overpayment. Receiving the results of a contractor or government audit is an example of credible information of a potential overpayment that requires the provider or supplier to conduct reasonable diligence to confirm or contest the audit's findings.

Comment: Some commenters requested clarification that the fact that a contractor or the government determines that a claim constitutes an overpayment does not automatically mean that the provider or supplier should have reported and returned the overpayment at an earlier time.

Response: As previously discussed, the threshold obligation in section 1128J(d) of the Act is that providers and suppliers shall report and return overpayments. For a claims-based overpayment, that obligation must be fulfilled within 60 days of identifying the overpayment. Section 401.305(a)(2) states that a person has identified an overpayment when the person has or should have determined, through the exercise of reasonable diligence, that the person has received an overpayment and has quantified the amount of the overpayment. Whether a particular provider or supplier has satisfied this standard in a particular circumstance is a fact-based inquiry.

Comment: Other commenters requested clarification that a provider's obligation to inquire about potential overpayments extends only to the results of the contractor or government audit and not to other similar potential overpayments.

Response: We agree that when receiving the results of a contractor or government audit, the scope of the duty to conduct reasonable diligence is defined by the issues that the contractor or government audited. However, providers and suppliers will need to review the specific facts and circumstances, including the billing and coverage rules, to determine the required scope of their reasonable diligence. Also, the contractor or government audit may be for a limited time period. If the provider or supplier confirms the audit's findings, then the provider and supplier may have credible information of receiving a potential overpayment beyond the scope of the audit if the practice that resulted in the overpayment also occurred outside of the audited timeframe. In such situations, providers and suppliers will need to conduct reasonable diligence within the lookback period of this rule to comply with section 1128J(d) of the Act.

Comment: Several commenters also stated that the duty to search for overpayments should not be triggered by a general government notice, such as the OIG annual work plan. Commenters requested that the final rule indicate that the duty to make a reasonable inquiry is only triggered by a notice of a contractor or government audit specific to a provider.

Response: If a contractor or government audit discovers a potential overpayment, the audit notice from the contractor or government triggers the provider's or supplier's obligations under section 1128J(d) of the Act. We encourage providers and suppliers to take advantage of additional sources of publicly available information, such as the OIG's annual work plan and CMS notices, to inform their planning of proactive compliance monitoring activities and retroactive reviews.

Comment: Many commenters requested clarification of the rule's application in the administrative appeal process. Some commenters recommended that providers and suppliers have the opportunity to review Medicare contractor audit results and determine whether they agree or whether they will file an appeal. Some commenters believed that the obligation to report and return overpayments identified by Medicare contractors should wait until the appeals process is completed. In support, commenters rely on Section 935 of the Medicare Modernization Act (MMA), which places limits on the ability of CMS and its contractors to recoup a potential overpayment during the first 2 levels of administrative appeal. Commenters requested that CMS clarify that, for the purposes of complying with proposed 42 CFR 401.305, a potential overpayment brought to the provider's or supplier's attention by a Medicare contractor shall not be considered ''identified'' until the later of: (1) The exhaustion of the provider's or supplier's appeal rights; or (2) the expiration of the time limit for the provider or supplier to pursue the next level of administrative or judicial appeal.

Response: The provisions of this final rule establish that a person has the responsibility to conduct an investigation in good faith and a timely manner in response to obtaining credible information of a potential overpayment and to return identified overpayments by the deadline set forth in § 401.305(b). This responsibility exists independent of the appeals process for contractors' overpayment determinations. We believe that contractor overpayment determinations are always a credible source of information for other potential overpayments. Moreover, we recognize that in certain cases, the conduct that serves as the basis for the contractor identified overpayment may be nearly identical to conduct in some additional time period not covered by the contractor audit. If the provider appeals the contractor identified overpayment, the provider may reasonably assess that it is premature to initiate a reasonably diligent investigation into the nearly identical conduct in an additional time period until such time as the contractor identified overpayment has worked its way through the administrative appeals process.

Comment: A number of commenters questioned whether providers and suppliers have appeal rights to self-identified overpayments. Commenters stated that the potential penalties for not reporting and returning an overpayment, coupled with the short 60-day time period for doing so, likely will result in providers and suppliers erring on the side of caution and returning an overpayment prematurely. Commenters suggested expanding the list of actions in 42 CFR 405.924 that constitute an initial determination to provide for an appeal right related to a ''contractor's acceptance of a refund of an overpayment made in accordance with § 401.305.'' Other commenters stated that the acceptance of the overpayment and the related adjustment should be considered a reopening and revised determination of the initial

determination of payment under the current regulations and CMS manual instructions. Other commenters stated that the concept of reconciliation should incorporate the existing appeals process.

Response: Section 1128J(d) of the Act clearly requires providers and suppliers to report and return identified overpayments they have received. To the extent that the return of any self-identified overpayment results in a revised initial determination of any specific claim or claims, a person would be afforded any appeal rights that currently exist, as some commenters stated. Revised initial determinations, which trigger appeal rights under the existing rules, are issued when specific claims are adjusted. We note the process for identifying an overpayment requires a person to exercise reasonable diligence in determining whether an overpayment was received and to quantify the overpayment amount with a reasonable degree of certainty. We expect persons to exercise responsibility in identifying an overpayment that is reported and returned in accordance with section 1128J(d) of the Act. It would be inconsistent with the intent of the statute and our regulations for persons to return self-identified overpayments or a subset of the larger overpayment, and then appeal those overpayments as a means to circumvent the duty for timely investigation of potential overpayments or the deadline for reporting and returning of identified overpayments. As such, we decline the commenters' suggestion to create an explicit appeal right by classifying ''contractor's acceptance of a refund of an overpayment made in accordance with § 401.305'' as an initial determination in § 405.924. If a provider or supplier were to report and return certain overpayments through individual claims determinations but chose not to extrapolate and, thus, not return the entire overpayment amount because the provider or supplier is appealing the individual claim determinations, then the provider or supplier could be viewed as failing to exercise reasonable diligence to identify amounts that the person should have determined are overpayments. As discussed in section II.C.1. of this final rule, any overpayment retained by a person after the deadline for reporting and returning the overpayment is an obligation that has the potential to trigger FCA liability.

Comment: Several commenters requested that CMS confirm that refunds based on statistical sampling will maintain appeal rights. Because individual claim adjustments may not be made when sampling is utilized to estimate an overpayment amount, CMS should confirm that providers and suppliers may still appeal such findings if necessary.

Response: To the extent that the return of any self-identified overpayment results in a revised initial determination of any specific claim or claims, a person would be afforded the appeal rights that currently exist. As is currently the case under the existing voluntary refund process, there are no appeal rights associated with the self-identified overpayments that do not involve identification of individual overpaid claims and individual claim adjustments.

Comment: Several commenters noted that the proposed rule provided no avenue for providers and suppliers to cancel the overpayment refund if the provider or supplier subsequently determines that the overpayment refund was made in error. Commenters suggested requiring contractors to return payments to providers and suppliers when the provider or supplier notifies the contractor that the funds were returned in error and requests a reversal.

Response: Providers and suppliers should exercise reasonable diligence as set forth in this final rule before reporting and returning the overpayment. Additionally, the existing reopening regulations afford a means for a provider or supplier to request correction of a mistake in reporting an overpayment, although we do not expect this to be a frequent occurrence.

2. Meaning of Applicable Reconciliation

Our proposed rule acknowledged 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 proposed § 401.305(c), we stated that ''applicable reconciliation'' would occur when the cost report is filed. This would include an initial cost report submission or an amended cost report. We proposed two exceptions to the general rule that the applicable reconciliation occurs with the provider's submission of a cost report. The first was related to Supplemental Security Income (SSI) ratios used in the calculation of disproportionate share hospital (DSH) payment adjustment. The second exception was related to the outlier reconciliation, which is performed at the time the cost report is settled if certain thresholds are exceeded.

Comment: Many commenters questioned our proposed interpretation of the term ''applicable reconciliation.'' Generally, commenters did not believe the Congress intended applicable reconciliation to be interpreted as narrowly as we proposed. Some commenters interpreted ''applicable reconciliation'' as the preliminary steps taken by the provider or supplier to determine whether they have received an overpayment. Some commenters suggested that CMS include the claims adjustment and credit balance processes in the definition of applicable reconciliation. Other commenters requested CMS to include all instances of addressing and resolving overpayments in the term ''applicable reconciliation,'' including but not limited to Medicare contractor or OIG audits and pre- and post-payment reviews by Medicare Administrative Contractors.

Response: We understand some of the commenters' concerns and believe our clarification of the constructive knowledge standard for identifying an overpayment discussed previously should address many of these concerns. However, we disagree with the commenters' interpretation of the term ''applicable reconciliation'' in the context of this final rule, which applies to Medicare Parts A and B. The term ''persons'' covered by section 1128J(d) of the Act is broad—it covers not only providers and suppliers, but also Medicaid managed care organizations, MA organizations, and PDP sponsors. The definition of overpayment, where the term ''applicable reconciliation'' is used, is similarly broad in that it covers overpayments received or retained by any of these persons. As a result, Congress addressed the significant differences between how all of these persons receive federal health care program dollars in the overpayment definition by including the term ''applicable reconciliation.'' Medicare Part A and B claims are submitted by providers and suppliers to contractors and those claims are expected to be correct when filed. Medicare contractors do not audit or ''reconcile'' every claim. To the extent our contractors perform claims auditing, that auditing is done in the context of our program integrity efforts to find improper claims. Section 1128J(d) of the Act does not permit providers and suppliers to retain overpayments until a CMS contractor or the OIG identify the overpayment for the provider or supplier. Providers and suppliers cannot rely on Medicare's contractors or the OIG to point out their overpayments for them—providers and suppliers are obligated to identify the overpayments they have received. Also, we do not believe that the claims adjustment and credit balance processes

are properly considered ''reconciliation.'' Instead, they are mechanisms for providers and suppliers to report and return overpayments that they identify. We have revised § 401.305(a)(2) to address those processes.

Comment: Some commenters stated that our proposed approach is inconsistent with our prior position in previous rulemakings that commenters contend allowed for post-payment adjustments before considering if an overpayment exists. Commenters cited language from the March 25, 1998 proposed rule (63 FR 14506) as an indication that CMS allowed reconciliation to occur prior to the remaining overpayment amount being considered a debt. The March 25, 1998 proposed rule specified that overpayments generally result when payment is made by Medicare for non-covered items or services, when payment is made that exceeds the amount allowed by Medicare for an item or service, or when payment is made for items or services that should have been paid by another insurer (Medicare secondary payer obligations). Furthermore, it specified that, once a determination and any necessary adjustments in the amount of the overpayment have been made, the remaining amount is a debt owed to the United States Government.

Similarly, commenters believed the following statement in our January 25, 2002 proposed rule (67 FR 3663) supports a more inclusive definition of applicable reconciliation: ''Submission of corrected bills in conformance with our policy, within 60 days, fulfills these requirements for providers, suppliers, and individuals.''

Response: The cited language from the March 1998 proposed rule was addressing the Secretary's identification of overpayments, not overpayment identified by a provider or supplier, which is the subject of this rule. As for the January 2002 proposed rule, we note that the structure proposed in that rule is similar to the section 1128J(d) obligation regarding the reporting and returning of overpayments within 60 days of identification. We fail to see how the sentence cited by commenters from the January 2002 proposed rule indicates anything about the concept of applicable reconciliation. Moreover, this statement is consistent with the discussion in section II.C.4. of this final rule regarding the claims adjustment processes as a way to report and return overpayments.

Comment: Many commenters questioned the proposed definition of ''applicable reconciliation'' as it pertains to cost reports. The proposed rule defined ''applicable reconciliation'' as occurring when a cost report is filed, except that any changes to the SSI ratio that affect the Medicare hospital disproportionate share payments and any reconciliation to outlier payments will not result in a refund obligation until such time as the final settlement of the hospital's cost report occurs. Specifically, commenters stated that section 1128J(d) of the Act recognizes the deadline for submission of the initial cost report as tolling the 60-day time period and thus applicable reconciliation should mean a process that occurs subsequent to the submission of the initial cost report.

Commenters stated that CMS' discussion of the applicable reconciliation period seemed to suggest that, other than for SSI ratios and outliers, providers will be expected to have identified a cost report-related overpayment at the time that the provider submits an initial or amended cost report. According to commenters, this suggestion is inconsistent with the purpose of the cost report settlement process, which is to assist all parties in identifying and correcting errors, and it is not until this process is completed (and sometimes long after) that providers may become aware of an overpayment. In addition, commenters objected to the position that initial or amended cost reports can serve as the basis for an overpayment, given that the determination of the amount of reimbursement due on that cost report is not final until the contractor audits the cost report and issues a written determination under 42 CFR 405.1803(a).

Commenters recommended ''applicable reconciliation'' in the context of cost reporting occur upon the final settlement of a provider's cost report by the MAC, so long as, upon discovery of an issue subject to cost report audits that could affect a provider's Medicare payment, the provider timely discloses the issue to a MAC for purposes of preparing a final cost report settlement.

Response: We appreciate the comments on this issue. However, we are finalizing the definition of applicable reconciliation as proposed. The applicable reconciliation for purposes of 1128J(d)(4)(B) is the reconciliation that enables a person to identify funds to which the person is not entitled. Providers are required to file annual cost reports in order to determine their total reimbursement and any amount due to or from the Medicare program. When a provider files its cost report, it is attesting to the accuracy of the provider's reconciliation of the interim payments and costs. Accordingly, in the context of cost reporting, the ''applicable reconciliation'' is the provider's year-end reconciliation of payments and costs to create the cost report. The cost report must be filed within 5 months of the end of the provider's fiscal year end, which allows the provider time to reconcile payments and costs and identify any funds to which the provider is not entitled. This overpayment should be returned at the time the cost report is filed. We note that this definition establishes a policy that is consistent with our regulations at 42 CFR 405.378(e)(2)(i), which state that if a cost report is filed indicating that an amount is due to CMS, interest on the amount due will accrue from the due date of the cost report (unless certain exceptions apply).

Comment: Several cancer centers raised concerns about the rule's application to their payments. According to comments, cancer centers are reimbursed for inpatient services based on the reasonable cost methodology subject to the Tax Equity and Fiscal Responsibility Act (TEFRA) cost limits and are eligible for hold harmless payments under the outpatient prospective payment system. Because of the unique aspects of these payment methodologies, billing or other errors or omissions that may cause an overpayment for other types of hospitals would often not result in a reduction in overall reimbursement for a cancer center if they were corrected. Therefore, commenters requested that CMS clarify that billing or other errors that would not impact the reimbursement amount that a provider receives would not constitute an overpayment for purposes of this final rule.

Response: We agree with the commenters to the extent that section 1128J(d) of the Act pertains only to overpayments. If a provider identifies an error or omission that does not result in an overpayment, then the requirements of section 1128J(d) of the Act or this rule do not apply.

Comment: Commenters questioned whether there is a duty to revise past cost reports based on the results of a MAC audit on one cost report. For example, a MAC may audit a cost report for one year and make certain adjustments based on what it determines to be the improper treatment of certain costs. Commenters questioned whether, under this rule, a provider would be required to submit amended cost reports for all other unaudited cost report years in which the provider treated those costs in a similar fashion.

Response: If the MAC notifies a provider of an improper cost report payment, the provider has received credible information of a potential overpayment and must conduct reasonable diligence on other cost reports within the lookback period to determine if it has received an overpayment.

Comment: Commenters questioned the rule's effect on the hospice annual cap, the home health outlier revenue cap, and requests for anticipated payments (RAPs). According to commenters, hospices and home health agencies have no way of knowing whether they have received a cap overpayment, or the amount, until they are notified by the MAC. Commenters requested that CMS clarify that the rule does not apply in these situations.

Response: The hospice and home health cap determinations are made at the end of the year and it is possible that the provider may not be aware of the cap status until their MAC calculates the final cap amount. Therefore, the provider is not responsible to report and refund the overpayment until they have received the cap determination from their MAC. There can be no applicable reconciliation until the final cap amount is determined.

Comment: Commenters questioned the rule's effect on payment adjustments under the long-term care hospitals (LTCHs) prospective payment system (PPS), including the so-called ''25-percent threshold rule'' payment adjustment policy as implemented by 42 CFR 412.534 and 412.536.

Response: In this final rule, we define overpayment as 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. To the extent the LCTH adjustments meet this definition they are overpayments.

Comment: Commenters questioned how providers that receive periodic interim payments (PIP) would be expected to return any overpayments. Under the statutory and proposed regulatory definitions of ''overpayment,'' during any cost reporting period, no overpayment exists until the provider submits its cost report. Commenters sought clarification that any overpayments identified by providers related to these interim payments must be reported and returned by the date any corresponding cost report is due, not within 60 days of identification. Commenters believed that the preamble language in the proposed rule indicated that CMS believed any overpayments associated with interim payments made to a provider throughout the cost report year would be reconciled at the time that the cost report is due, but they sought confirmation that this is CMS's policy for PIP providers.

Response: We agree with commenters. Overpayments as a result of PIP payments would be reported and returned at the time the initial cost report is due. There is no applicable reconciliation until the PIP payments are dealt with in the cost report process. However, if a provider is aware that their PIP payment may not be accurate, they should continue with normal business practices and inform its MAC of the issue.

Comment: Some commenters questioned under what circumstances a provider would anticipate an outlier reconciliation will be performed at the time of cost report settlement and requested that CMS clarify that outlier payments may be returned via the overpayment reporting process for claims. Other commenters requested clarification of how the rule would apply in situations where a MAC amends the provider's cost to charge ratio resulting in a reduction to its Medicare outlier payments for the cost reporting period. Specifically, commenters questioned whether it is the provider's responsibility to recompute its outlier payments based on this new information and remit any overpayment to the Medicare contractor within 60 days of receiving the notification or whether the provider should wait for the MAC to audit, or if applicable, reopen the cost report and redetermine the settlement amount.

Response: An overpayment as a result of an outlier reconciliation would be identified once the provider receives that information from its MAC as part of the cost report settlement process. The provider is not responsible for attempting to identify the cost report outlier reconciliation overpayment in advance of the MAC's reconciliation calculation. However, for claims, if the provider identifies an inaccurate outlier claim payment, the provider must follow the overpayment payment reporting process for claims, as noted in this final rule.

Comment: Given that cost reports can remain under audit review for 3 to 4 years and are not finalized until the Notice of Program Reimbursement (''NPR'') date, commenters requested that CMS provide guidance on providers' responsibilities when an overpayment is discovered by the provider or the MAC auditor after the cost report is due/filed but prior to the NPR date. Commenters questioned whether the provider would be required to report and repay the overpayment within 60 days of identification rather than allowing for completion of the audit process, which includes netting out of underpayments and overpayments, while the cost report is still open. Commenters stated that requiring reporting and returning within 60 days of identification, as opposed to allowing completion of the audit process, would force providers to send in numerous overpayments for minor errors while the cost report is open and disrupt the normal MAC audit process.

Commenters also questioned a number of other cost report issues that they believed to be not entirely known to the provider at the time of initially filing the as-filed cost report, but which are reconciled through the audit process, and finalized with the issuance of the NPR, including—

- Home office cost statements (HOCS), providers usually file an estimate of home office costs on the hospital cost report, which is subsequently reconciled to the HOCS when the MAC audits the HOCS;
- Any interim payments such as Medicare bad debt or graduate medical education (GME), including resident ''overlap'' reports from the MAC;
- Sole-community hospital (SCH)/Medicare-dependent hospital (MDH) payments;
- End-stage renal disease (ESRD) payments;
- Organ payments;
- Nursing and allied health payments;
- Tentative settlement payments;
- Updated Provider Statistical & Reimbursement Report (PS&R) for claims processed after cost report submission;
- Prior-year audit adjustments, CMS rulings, and PRRB appeals; and
- HITECH Act EHR incentive payments.

Response: If the provider self-identifies an overpayment after the submission and applicable reconciliation of the Medicare cost report, it is their responsibility to follow the procedures in this rule, and report and return the overpayment within 60 days of identification. The provider must use the applicable reporting process for cost report overpayments (submit an amended cost report) along with the overpayment refund. The amended cost report must include sufficient documentation and data to identify the issue in order for the MAC to adjust the cost report.

If the overpayment is identified by the MAC during the cost report audit, the MAC will determine and demand the exact amount of the overpayment at

final settlement of the cost report. The provider remains responsible to report and refund similar overpayments in cost reports for other years not covered by the MAC audit.

Comment: Commenters noted that the proposed rule did not mention any changes to the cost report reopening period at § 405.1885, which is 3 years.

Response: We did not propose and are not changing the time period in 42 CFR 405.1885.

3. Lookback Period

Proposed § 401.305(g) specified 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 proposed 10 years because this is the outer limit of the FCA statute of limitations. We also proposed amending 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 to ensure consistency between the reopening regulations and § 401.305(g).

Comment: Many commenters objected to the proposed 10-year lookback period in § 401.305(g) for several reasons. First, commenters stated that section 1128J(d) of the Act does not provide a basis to create a new lookback period that is different from the one in existing reopening rules. Second, commenters stated that it was not appropriate to use the outer limit of the FCA as the lookback period. Since the FCA is a fraud enforcement statute, commenters stated that it was not appropriate to apply this time period to all overpayments, which could also be caused by errors or mistakes that did not rise to the level of fraud. Third, commenters stated that 6 years is the more commonly used statute of limitations in the FCA and that the 10-year period only applied in certain circumstances. Thus, commenters stated that the proposed lookback period was broader than, and not parallel to, that of the FCA.

Commenters also stated that the proposed 10-year period was overly burdensome. First, many commenters stated that compliance with the proposed time period would require a de facto 10-year record retention requirement and would be inconsistent with existing record retention requirements. Second, commenters stated that maintaining paper and electronic medical and billing records for the proposed 10-year period as well as the difficulties with retrieving that information from legacy systems would be costly and time-consuming. Third, commenters stated that the proposed 10-year period would increase the burden, costs, and complexity in investigating a potential overpayment. For example, commenters noted that they would likely need to create very large sample sizes to cover a 10-year timeframe. In addition, the review would need to account for any changes in the coding, including Current Procedural Terminology (CPT) codes (or other codes used to identify items or procedures billed), Correct Coding Initiative (CCI) editing protocols, local contractor determinations, coverage guidelines, and other CMS policies. Finally, commenters noted that staff turnover at both the provider or supplier and CMS contractor levels may create additional challenges in investigating claims filed up to 10 years ago.

Commenters offered a variety of alternative lookback periods:

- Many commenters suggested using the current reopening rules at 42 CFR 405.980, which permit contractors to reopen claims within 1 year for any reason, within 4 years for good cause, and at any time if evidence of fraud or similar fault exists. These commenters stated that § 405.980 sets forth a reasonable timeframes and providers and suppliers have built their internal processes around them.
- Other commenters recommended a 3-year lookback period for all overpayments not resulting from fraud or other intentional misconduct. These commenters generally justified a 3-year period because the Medicare and Medicaid RACs are limited to 3 years in their audits. A commenter recommended 3 years because it matched the timeframe for coordination of benefits under Part D.
- Other commenters recommended a 5-year period because it was consistent with the medical record retention requirement in the hospital conditions of participation at 42 CFR 482.24.
- Other commenters recommended a 6-year period. These commenters stated that 6 years is consistent with the more commonly applicable FCA statute of limitations as well as the statute of limitations for section 1128A of the Act, which contains a variety of civil monetary penalty (CMP) authorities applicable to Medicare and Medicaid, including the CMP applicable to section 1128J(d) of the Act. Several commenters also recommended 6 years because it is consistent with the medical record retention requirements for Part B providers under Chapter 24, 30.2 of the Medicare Claims Processing Manual and the HIPAA requirements at 45 CFR 164.316(b)(2) for maintaining documentation of compliance policies and procedures as well as various state medical record retention requirements.
- Other commenters recommended a 7-year period. These commenters stated that most, if not all, providers and suppliers retain documentation for claims they submit for a 7-year period as part of their standard record retention policies.

Response: We have carefully considered all of the comments on the lookback period and have concluded that 6-year time period is most appropriate for this rule. The change is reflected in § 401.305(f) of this final rule. The 6-year lookback period will be measured back from the date the person identifies the overpayment. As an initial matter, we believe that we have the authority to establish a lookback period for section 1128J(d) of the Act under our programmatic rulemaking authority, including our authority to create the reopening rules under section 1869 of the Act. We note that section 1128J(d) has no time limit to the obligation to report and return overpayments received by a provider or supplier. The enforcement mechanisms, the FCA and section 1128A of the Act, have time limits ranging from 6 to 10 years. We believe that the current reopening rules need to be adjusted to properly reflect section 1128J(d) of the Act, specifically the statute's enforcement aspects. We are amending the reopening rules to provide for a reopening period that accommodates the 6-year lookback period for reporting and returning overpayments, and to ensure that the reopening rules do not present an obstacle or unintended loophole to compliance and enforcement of section 1128J(d) of the Act. We specify in § 405.980(c)(4) that providers may request that contractors reopen initial determinations for the purpose of reporting and returning an overpayment under § 401.305. However, this revision to the reopening regulation does not extend the lookback period specified in § 401.305(f). Rather, it serves to make administrative accommodations so that contractors may reopen the initial determination associated with any overpayment reported and returned by a provider or supplier during the 6-year lookback period set forth in this final rule.

After review of all the issues identified by the commenters, we conclude that a 6-year lookback period would appropriately address many of the concerns about burden and cost outlined previously. Specifically, we note that, according to commenters, many providers and suppliers retain records and claims data for between 6 and 7 years based on various existing

federal and state requirements. Thus, we believe our final rule does not create additional burden or cost on providers and suppliers in this regard. Also, 6 years is consistent with one component of the FCA statute of limitations as well as the statute of limitations under section 1128A of the Act.

Comment: Several commenters recommended a lookback period that is no longer than the state medical record retention law in which the medical professional or facility is licensed and is not longer than 7 years from the date of service.

Response: We decline to adopt this approach for the reasons discussed previously. In addition, we do not believe it is appropriate or desirable to have the time period vary based solely on the medical record retention laws of the state in which the provider or supplier is furnishing services. Section 1128J(d) of the Act uniformly applies to all providers and suppliers in each state and, as such, all providers and suppliers should have the same obligations.

Comment: A commenter recommended changing the reopening rules to eliminate the ability to reopen claims at any time for fraud or similar fault and instead modify reopening rules to be a 4-year lookback period for errors that are not the result of fraud or similar fault, a 6-year lookback period (consistent with one component of the FCA statute of limitations) for knowingly false or fraudulent claims, and a 10-year lookback period (consistent with the outer limit of the FCA statute) for the most extreme cases where knowingly false or fraudulent claims have been actively concealed from discovery.

Response: We also decline to adopt this approach for the reasons discussed previously. In addition, we see no reason to change the ''fraud or similar fault'' aspect of the reopening rule. First, this issue is outside the scope of this rulemaking. Second, we do not believe changing this aspect of the reopening rule is necessary or desirable. We note that fraud investigations and judicial proceedings can require an extended period of time beyond the date the claim was filed to resolve, which counsels against imposing a limitation on reopening determinations procured by fraud or similar fault.

Comment: Several commenters noted that in 2005 we considered extending the reopening periods to 5 years in certain circumstances and decided not to. Specifically, we proposed a 5-year reopening period if a contractor discovered a pattern of billing errors or identified an overpayment extrapolated from a statistical sample. (See the November 15, 2002 proposed rule (67 FR 69327).) In response to this proposed provision, commenters maintained that we did not adequately justify the proposed 5-year timeframe and expressed concerns about the difficulty and burden of locating documentation on older claims. (See the March 8, 2005 interim final rule with comment period (70 FR 11452).) In the interim final rule, we did not finalize the 5-year proposed period. Commenters questioned why we proposed a lookback period twice the length of the period proposed, and not finalized, in 2005 and suggested that we refrain from extending the look-back period for reported overpayments to 10 years for the same reasons.

Response: In the March 2005 interim final rule, we stated that we proposed the 5-year lookback period in an effort to accommodate overpayments identified by external auditors and law enforcement agencies where the external or law enforcement auditor used a 5-year sampling methodology, but the Medicare contractor was limited to a 4-year recovery period where there was no fraud determination. We decided to remove the proposal in recognition of commenters' concerns and directed contractors to rely on the similar fault provisions to reopen claims where law enforcement findings suggest a need to reopen. Since the March 2005 rulemaking, the Congress has changed the law by enacting section 1128J(d) of the Act. We believe that this law requires us to re-examine our reopening rules to ensure that those rules are consistent with the law. Previously in this final rule, we have articulated a rationale for the 6-year period in a way that balances giving full effect to the law the Congress passed with the cost and burden issues identified by commenters.

Comment: Commenters questioned whether they had a responsibility to go back beyond the 3 years covered in a Recovery Audit Contractor (RAC) audit that identifies overpayments.

Response: Yes, as discussed previously, this final rule clarifies that when the provider or supplier receives credible information of a potential overpayment, they need to conduct reasonable diligence to determine whether they have received an overpayment. RAC audit findings, as well as other Medicare contractor and OIG audit findings, are credible information of at least a potential overpayment. Providers and suppliers need to review the audit findings and determine whether they have received an overpayment. As part of this review, providers and suppliers need to determine whether they have received overpayments going back 6 years as stated in this rule.

Comment: A commenter requested that, regardless of the lookback period we adopt, we allow Part B providers to use scanned records to justify their Part B claims for auditing purposes. The commenter stated that maintaining paper records for 6 or 10 years is burdensome, takes up significant physical space and is unnecessarily costly in terms of the cost of renting or purchasing space to store 6 or 10 years' worth of paper records. The commenter noted that the proposed rule was silent as to whether scanned versus paper records are sufficient for validating claims under the lookback period and requested clarification that scanned records are acceptable for validating claims.

Response: We agree with the commenter that scanned or electronic records are acceptable for validating claims for purposes of identifying overpayments within the context of this rule.

Comment: Several commenters believed that the 10-year lookback period was appropriate. Commenters believed that the proposed rule was consistent with the 10-year FCA statute of limitations and would help ensure wrongfully retained overpayments were returned to the government. Commenters noted that the 10-year FCA provision has been in place since the 1986 amendments, and thus does not impose new burdens or duties on providers and suppliers. Commenters stated that an alternative period would lead to unnecessary confusion and inconsistencies in light of existing expectations of liability for a 10-year lookback period.

Response: We appreciate the commenters' perspective and agree that a 10-year lookback period would be a justifiable option for this final rule. However, we have decided to adopt a 6-year period for the reasons discussed previously.

Comment: A few commenters sought clarification of the proposed reopening rule change insofar as whether it affects the existing reopening rules for contractors reopening paid claims beyond 4 years. Commenters stated that they believed the proposed revision to the reopening rules was intended to eliminate an administrative hurdle that would otherwise prevent the contractor from adjusting claims following receipt of an overpayment disclosed by a provider. Commenters interpreted the revision to the reopening rules to not expand the authority of contractors to reopen paid claims that are not the subject of a voluntary disclosure by a

provider and requested that we confirm that interpretation in the final rule.

Response: We agree with the commenters' interpretation. The proposed rule amended § 405.980(b), which applies to reopenings initiated by the contractor. In the context of this final rule, providers or suppliers would be initiating the reopening by reporting and returning the overpayment, which falls under § 405.980(c). As such, we have included language concerning reopenings under this final rule in § 405.980(c)(4) for clarity. Reopenings under this subsection are limited to reopenings requested by the provider or supplier under § 401.305.

Comment: A commenter requested clarification of the statement in the preamble indicating that overpayments reported in accordance with § 401.305 may be reopened for a period of 10 years. The commenter suggested this statement could mean that the decision to adjust a paid claim following the report of an overpayment would be subject to revision for 10 years after the adjustment is made. The commenter requested that we clarify that claims reported as overpayments in accordance with § 401.305 may be reopened for a period of 10 years after the date the claim was paid.

Response: Consistent with the lookback period specified in § 401.305, any initial determination that is subsequently reported and returned as an overpayment is subject to reopening and revision by a contractor whenever the overpayment is returned.

Comment: A commenter questioned whether the adjustment to a paid claim following a provider's report and return of an overpayment constitutes a redetermination for purposes of the reopening rules.

Response: An adjustment to any individual paid claim constitutes a revised initial determination for purposes of the reopening rules.

Comment: Several commenters noted that the Medicare hospital conditions of participation at 42 CFR 482.24 requires hospitals to retain medical records for 5 years and requested clarification on how (if at all) the implementation of the proposed 10-year lookback period impacts or alters recordkeeping rules.

Response: First, we note that § 482.24(b)(1) states that hospitals must retain medical records for a period of at least 5 years, which sets a minimum record retention period, not a maximum. We also note that, as discussed previously, other commenters cited other record retention rules and practices for 6 to 7-year periods. Since we are establishing a 6-year lookback period, we believe hospitals will have little, if any, additional record retention burden as the result of this rule.

Comment: A commenter recommended that any lookback period be phased-in over a series of years to balance the need for the return of Medicare overpayments with the amount of time medical groups need to prepare for such a change. The commenter stated that a phase-in period would provide medical groups with a greater transition period to adjust their record retention policies and develop additional efficiencies to ensure that the identification, quantification, and accuracy of Medicare overpayments are not compromised.

Response: Given our finalized lookback period, we do not believe a phase-in period is necessary or appropriate.

Comment: Several commenters requested clarification on whether this rule is retroactive. More specifically, commenters questioned how this rule would apply to overpayments received prior to—(1) March 23, 2010, the effective date of section 1128J(d) of the Act; and (2) the effective date of the final rule. Commenters frequently posed these questions in conjunction with objecting to the proposed 10-year lookback period. First, commenters stated that they believed retroactive application of the rule to overpayments received prior to March 23, 2010 would not be legally supportable because the Affordable Care Act does not indicate that section 1128J(d) of the Act applies retroactively. In addition, commenters believed that the Secretary was not given retroactive rulemaking authority here.

Response: Section 1128J(d) of the Act is not retroactive; thus, failure to comply with the specific requirements of this section prior to March 23, 2010 is not a violation of this statutory provision. However, we note that other statutes governed the disposition of overpayments prior to the enactment of the Affordable Care Act. We do not address here compliance with such other statutory provisions. Beginning on March 23, 2010—the enactment date of the Affordable Care Act and section 1128J(d) of the Act—providers and suppliers that had not already returned a particular overpayment were required to report and return the overpayment in accordance with the provisions of section 1128J(d) of the Act. This requirement exists even if the provider or supplier received the overpayment prior to March 23, 2010.

Similarly, this final rule is not retroactive. Providers and suppliers that reported and/or returned overpayments prior to the effective date of this final rule and that made a good faith effort to comply with the provisions of section 1128J(d) of the Act are not expected to have complied with each provision of the final rule. However, all providers and suppliers reporting and returning overpayments on or after the effective date of this final rule—even overpayments received prior to the rule's effective date—must comply with the new regulatory requirements.

For example, self-referral overpayments reported to us in accordance with the CMS Voluntary Self-Referral Disclosure Protocol (SRDP) prior to the effective date of this final rule will not be governed by the 6-year lookback specified in this final rule. This includes both overpayments reported and returned (via compromise and settlement) as well as those reported and still in the process of being reviewed through the SRDP. Providers and suppliers that made a good faith effort to comply with section 1128J(d) of the Act by reporting self-referral overpayments to the SRDP, which, until now, has operated with a 4-year lookback period, are not expected to return overpayments from the fifth and sixth year through other means. Providers and suppliers reporting overpayments to the SRDP on or after the effective date of this final rule are subject to the 6-year lookback period specified in this final rule. However, at this time, we are only authorized under the Paperwork Reduction Act to collect financial analysis of overpayments that occurred during a 4-year lookback period. In connection with this final rule, we are seeking authorization from OMB to collect financial information regarding overpayments using the 6-year lookback period. Until the revised collection is approved by OMB, providers and suppliers reporting overpayments to CMS in accordance with the SRDP have no duty to provide financial information from the fifth and sixth years, that is, the 2 years outside of the currently authorized 4-year lookback period. Accordingly, until notification of changes to the SRDP lookback period, providers and suppliers submitting to the SRDP may voluntarily provide financial information from the fifth and sixth years or report and return overpayments from the fifth and sixth years through other means.

There are two time periods of concern to commenters—the time prior to the enactment of the Affordable Care Act on March 23, 2010 and the time period between March 23, 2010 and the effective date of this final rule. For the time prior to March 23, 2010, while providers and suppliers had an existing

obligation to return overpayments, the specific obligations contained in section 1128J(d) of the Act are not retroactive prior to March 23, 2010. Therefore, failing to report and return overpayments within the deadline in section 1128J(d) of the Act would not be actionable prior to March 23, 2010. The obligations of section 1128J(d) of the Act were effective March 23, 2010. Thus, providers and suppliers were obligated to comply with section 1128J(d) of the Act as of that date. For the time period between March 23, 2010 and the effective date of this final rule, providers and suppliers may rely on their good-faith and reasonable interpretation of section 1128J(d) of the Act.

Comment: Some commenters suggested that providers with a ''certified'' or ''approved'' compliance program should not be subject to the lookback period because commenters stated that any overpayment would be caused by a simple mistake and not fraud or abuse.

Response: We see no justification in section 1128J(d) of the Act for the commenters' suggestion. As we stated earlier, section 1128J(d) of the Act requires the reporting and returning of all overpayments received by a provider or supplier.

Comment: Many commenters expressed concerns that certain requirements in the proposed rule, particularly the proposed lookback period, would increase the administrative burden on providers and suppliers, which would lead to increased operating costs and may lead to certain providers and suppliers opting out of Medicare. Commenters expressed concerns about the overall tone of the proposed rule as one that appeared to assume that all overpayments are caused by fraud and abuse. Commenters stated that most providers and suppliers are honest and use their best efforts to submit claims to Medicare that are appropriate. Some commenters characterized the proposed rule as a ''one-size-fits-all'' approach that did not take into account the differences between large and small providers and suppliers or providers and suppliers that CMS has designated as lower fraud risks.

Response: We appreciate all the comments and have amended the final rule to take many of these comments into account, as discussed elsewhere in this final rule. We understand the concerns expressed and have fashioned the final rule to balance concerns raised by commenters with fulfilling the requirements and purpose of section 1128J(d) of the Act. The final rule contains flexible yet strong standards that can be applied to many different circumstances and providers and suppliers. The statute and this rule are not limited to overpayments caused by fraud or abuse.

4. How To Report and Return Overpayments

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

In § 401.305(e)(1), we proposed to require the use of the existing voluntary refund process, which will be renamed the ''self-reported overpayment refund process,'' set forth by the applicable Medicare contractor to report and return overpayments except as provided in § 401.305(e)(2). Section 401.305(e)(2) provided that a person would satisfy 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. The existing voluntary refund process is referenced in Publication 100–08, Chapter 4, Section 4.16 of the Medicare Program Integrity Manual. Under the existing voluntary refund process, providers and suppliers report overpayments using a form that each Medicare contractor makes available on its Web site.

In § 401.305(d) of the February 16, 2012 proposed rule (77 FR 9179), we also proposed a specific list of 13 data elements that were required in the report: (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) 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; and (13) a refund in the amount of the overpayment. We recognized that some of the current reporting forms may differ among the different Medicare contractors and stated we planned 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, we stated in the preamble that providers and suppliers should utilize the existing form available from the Web site of the applicable Medicare contractor.

Comment: Many commenters appreciated CMS' use of an existing process, the voluntary refund process, as the method for reporting and returning overpayments. Generally, commenters agreed that using an existing process to implement the 60-day rule will ease the burden for reporting and returning overpayments. However, many commenters requested clarification about how this rule affected other existing processes that enable providers and suppliers to report and return claims-based overpayments. Commenters confirmed that providers and suppliers sometimes use the voluntary refund process. Commenters also noted that this process is not the only way to make overpayment refunds and is usually only used when a refund is made by check and the overpayment was calculated using a sampling methodology.

Commenters stated that, in most overpayment cases, other processes are used that are effective and efficient both for the Medicare program and providers and suppliers. Commenters repeatedly noted the claims adjustment and reversal process for Part A and B claims. The claims adjustment process for Part A claims is electronically accomplished through access to the Fiscal Intermediary Standard System (FISS). The claim adjustment is then recorded on the Provider Statistical & Reimbursement Report (PS&R). Commenters uniformly stated that it is critical that providers and suppliers be permitted to continue to use the claims adjustment process to refund overpayments, when appropriate, to ensure that the claims data is adjusted in the FISS. Claims adjustment for Part B claims is currently a paper-based process, but one in which commenters stated providers and suppliers frequently use. In both Part A and B, claims adjustments include an adjustment reason code on the claim. The claim is reprocessed and the overpayment is recouped via the remittance advice.

In addition, commenters noted that hospitals are required to submit the

Medicare Credit Balance Report (CMS–838; OMB control number 0938–0600) within 30 days of the close of each calendar quarter to disclose any credits due to the Medicare program as a result of patient billing or claims processing errors, for example, being paid by Medicare and another payer for the same services, or overpayments resulting from incorrect calculation of the beneficiary's deductible or coinsurance. Any amounts due to Medicare must be repaid or claims adjusted at the time the CMS–838 is filed.

Commenters suggested that CMS permit the use of the claims adjustment and credit balance report process for returning overpayments because these existing processes are well-known to providers, suppliers, and Medicare contractors and work effectively and efficiently for all parties at recouping overpayments. In many commenters' experience, Medicare contractors prefer that providers and suppliers submit adjusted bills so that each beneficiary's account properly reflects how and why the payment was adjusted or how the contractors recouped a full or partial overpayment.

Response: We agree with commenters and amended the final rule accordingly in § 401.305(d)(1) by allowing for additional processes beyond the voluntary refund process. Providers and suppliers may use the claims adjustment, credit balance, self-reported refund process, or another appropriate process to report and return overpayments. This position preserves our existing processes and preserves our ability to modify these processes or create new processes in the future.

Comment: Commenters requested clarification on how the timing of the credit balance reporting process interacts with the timing of the report and return obligation in the proposed rule. Under the credit balance reporting process, the credit balance report is due 30 days after the end of each quarter, which would mean that overpayments received during the first 2 months of each quarter may be reported after the 60-day time period under the proposed rule has passed. Commenters requested guidance on how to comply with the proposed rule and follow the credit balance reporting process.

Response: We have revised the requirement to include the credit balance reporting process as a way to report and return overpayments under this final rule.

Comment: Some commenters requested that CMS permit electronically correcting or adjusting claims for the self-reported refund process as opposed to completing a form, cutting a check, and mailing it to the contractor for processing. It would reduce the administrative burden and allow for expeditious return of overpayments, while furthering the move to electronic processing of records.

Response: We will continue to review our processes and will consider this suggestion in future process improvements. Any changes to our administrative processes, including the self-reported refund process, will be addressed in the applicable manual.

Comment: Commenters questioned whether, instead of submitting a check with the overpayment reporting form, a provider continue to be able to request a voluntary offset.

Response: Yes, providers and suppliers may request a voluntary offset from the contractor.

Comment: Several commenters questioned how providers and suppliers should handle delays by the Medicare contractor in processing the refund, whether submitted through the electronic claims adjustment system, filing of the CMS–838, or by submitting a check or requesting an offset through the self-reported refund process. Commenters reported that there is great variability in how the contractors handle voluntary refunds. Some commenters reported that contractors at times have returned a refund check submitted by a provider or supplier or refused to accept it. Other commenters noted that some contractors claimed to be unable to process a refund if the claims were for a time period before that particular company was engaged as the contractor. Commenters requested that the rule should be modified to expressly state that a provider or supplier satisfies its repayment obligation under the statute and the rule by making good faith efforts to submit a valid form of payment to the contractor or government entity that the provider or supplier reasonably believes to be the appropriate recipient of a particular repayment. Other commenters suggested that the contractor inform the provider or supplier when it has preliminarily determined that the overpayment report complied with the rule. Commenters also suggested a processing deadline for the contractors.

Response: We agree with commenters that the obligations of this final rule are satisfied when the provider or supplier follows the appropriate process for the overpayment issue in good faith to report and return the overpayment, including calculating the amount of the overpayment. Publication 100–08, Chapter 4, Section 4.16 of the Medicare Program Integrity Manual requires contractors to process all voluntary refunds. The Program Integrity Manual specifically prohibits contractors from returning voluntary refund checks. We see no basis for a contractor to refuse a refund because a different company was the contractor during the period covered by the refund. Finally, we may consider a processing deadline for contractors in the future.

Regarding obtaining a preliminary determination, we believe contractors may not be able to conclude whether the overpayment refund complied with this rule on the face of the report. The provider or supplier is ultimately responsible for complying with this rule. Contractors are instructed to refer suspected fraud to law enforcement. Any overpayment refund does not negate any potential liability the provider or supplier may have for the overpayment issue.

Comment: Several commenters raised the situation where a contractor notifies a provider or supplier of an overpayment due to the contractor's error. Commenters stated that in this situation, where the contractor identifies and takes responsibility for collecting the overpayment by adjusting claims, the provider or supplier should not also be required to conduct an inquiry and report and return the overpayment on its own. Commenters noted that it may take the contractor more than 60 days to adjust the claims related to its error.

Response: We agree that where the contractor identifies a payment error by the contractor and notifies the provider or supplier that the contractor will adjust the claims to correct the error, the provider or supplier does not need to report and return the overpayment separately.

Comment: Many commenters objected to the proposed list of data elements in § 401.305(d) for several reasons, including that the data elements exceed the statutory requirements, are not necessary for Medicare to reconcile the payments, and create unnecessary burden. Commenters believed that the proposed list exceeded the requirements of section 1128J(d)(1)(B) of the Act, which states that the person must notify the Secretary in writing of the reason for the overpayment. Commenters specifically objected to the following items in the list of data elements in § 401.305(d) as overly burdensome: (3) How the error was discovered; (9) description of the corrective action plan to ensure the error does not occur again; and (12) if a statistical sample was used to determine the overpayment amount, a description of the statistically valid

methodology used to determine the overpayment. The discovery and corrective action plan elements were objected to because commenters stated that these elements appeared to assume that the overpayment were the fault of the provider or supplier. Overpayments may be caused by various reasons for which a corrective action plan is not necessary, such as an error or a routine adjustment, according to commenters. In addition, commenters noted that requiring claim-specific data, such as the date of service, health insurance claim number, and the Medicare claim control number for all of the claims associated with the overpayment would be impossible when a sampling and extrapolation methodology are used. Finally, commenters stated that compliance with the proposed reporting requirements would result in additional time and expense in reporting.

Response: We appreciate the comments and have adjusted the final rule in several ways. As discussed previously, this final rule permits using the most applicable process set forth by the Medicare contractor to report and return overpayments. As a result, we eliminated the specific list of data elements from the rule as proposed in § 401.305(d) to accommodate these existing processes. While we believe that the facts about how the overpayment was discovered and corrective action plans are relevant information relating to the reason for the overpayment, and thus within the purview of the statute, we also recognize that the additional burden of providing this information may not be necessary in all overpayment situations. In addition, we note that providers and suppliers submitting self-disclosures to the OIG Self-Disclosure Protocol (SDP) and the CMS Voluntary Self-Referral Disclosure Protocol (SRDP) must use the reporting process described in the respective protocol.

However, we continue to believe that, where the overpayment amount is extrapolated based on a statistical sampling methodology, it is necessary for the overpayment report to explain how the overpayment amount was calculated. The statute requires the return of an amount of money for the overpayment; therefore, it is a reasonable interpretation of the statute to require an explanation of how the overpayment amount was calculated by the provider or supplier by extrapolation. As commenters noted, statistical sampling is already used by providers and suppliers in the voluntary refund process. Therefore, we believe that requiring an explanation of the statistical sampling methodology results in little, if any, additional burden.

Comment: Many commenters stated that the differences between the regulatory requirement in proposed § 401.305(d) and various contractors' existing voluntary refund forms created confusion. Specifically, commenters requested clarity on how the provider or supplier could comply with the regulation by using a contractor form that did not contain all of the elements required by the regulation. Commenters noted that we stated in the preamble that we intended to create a standardized reporting form in the future and, until we issued a standardized reporting form, providers and suppliers should utilize the existing form available from the Web site of the applicable Medicare contractor. Commenters requested guidance on whether they would need to supplement the contractor's form to include any missing regulatory elements to be in compliance with the regulation. Many commenters expressed this concern in connection with using sampling to calculate the overpayment. These commenters noted that, when a provider or supplier identifies a systemic error, it is frequently most efficient and effective to determine the overpayment amount utilizing extrapolation. In such cases, commenters noted that it would be impossible to identify specific data items, such as specific dates of service and Medicare claim control numbers, for claims included in an extrapolation estimate other than for the specific claims in the sample. Thus, many commenters requested that we create an exception in the regulation to identify the data elements that were required only as appropriate, such as health insurance claim and Medicare claim control numbers, and specific dates of service. In addition, many commenters requested that we create the standardized refund form before or at the same time as issuing the final rule to avoid confusion and potential inconsistency among the contractors in the way that overpayments are handled.

Response: We recognize commenters' concerns and believe the revisions presented in this final rule address these concerns. We removed the proposed data element list from the regulation to eliminate confusion between compliance with the regulation and compliance with the applicable refund process, with the exception of the statistical sampling methodology explanation. We understand that providers and suppliers currently report extrapolated overpayments through the current voluntary reporting process. In these circumstances, providers and suppliers should make a good faith effort to provide the information on their contractor's refund form, which would include providing details of the statistical sampling methodology and indicating that certain data elements, such as health insurance claim and Medicare claim control numbers, are not available for all the claims in an extrapolation. Providers and suppliers should continue to report extrapolated overpayments through currently available methods. Given these changes, we do not believe it is necessary to create a standardized refund form for the self-reported refund process prior to finalizing this rule. We will work with the contractors to adjust their current forms and instructions to address the requirements of § 401.305(d) and will consider creating a standardized form in the future.

Comment: Several commenters stated that we should add a section on the refund form to allow a provider or supplier to indicate that it is reporting an overpayment as ''contested'' or ''with reservations'' to meet the 60-day deadline while allowing further investigation. This would provide the opportunity for providers and suppliers to document they do not agree that the reported amount is an overpayment, and yet, are reporting and returning the payment to ensure that they are in compliance with the rule.

Response: We decline to accept the commenters' suggestion. Providers and suppliers are reporting and returning overpayments that they have identified. Thus, we see no purpose in designating a refund as contested or with reservations.

Comment: Some commenters requested that we direct contractors to accept one single refund form with an attachment that contains the required elements on a spreadsheet. Commenters stated that the current refund process requires providers and suppliers to complete a single refund form for each account identified as an overpayment, resulting in an extensive resource burden with no value.

Response: We agree with the commenter that the practice they describe (submitting one form and attaching a spreadsheet containing the appropriate data) is acceptable for complying with this final rule.

Comment: Some commenters recommended that we create a process for providers and suppliers to report potential overpayments without a requirement to return the overpayment pending further review by the contractor or the government. Commenters acknowledged that the requirement that providers and suppliers report and

refund an overpayment is consistent with the statutory language. However, commenters recommended that CMS consider situations where it is not easy to determine whether the identified issue is an overpayment. The commenters recommended that we create a process permitting the submission of a written report to the Medicare contractor, which would satisfy the rule's reporting obligation. The Medicare contractor would then review the report to determine whether an overpayment existed, at which time the returning obligation requirement would be triggered.

Response: We decline to adopt the commenters' suggestion. As the commenters acknowledge, section 1128J(d) of the Act requires providers and suppliers to report and return overpayments they have received. It does not cover overpayments determined and demanded by a Medicare contractor or government agency.

Comment: A commenter recommended that we remove the reference to statistical samples because it may be interpreted to suggest a statistically valid sample is always required. The commenter stated that there are many situations where the size of the potential overpayment is small and does not warrant the expense of creating a statistical sample to calculate a refund amount. In these situations, the commenter believes providers and suppliers should do the best job they can to estimate the overpayment and give all benefit of the doubt to the government. The commenter believes requiring statistical validity for all estimated refunds will create the largest burden on small providers and suppliers. The commenter suggested that the final regulation instead require the explanation of the methodology used in any sample to protect the government's interest.

Response: We decline to adopt the commenter's suggestion. We structured the final rule to have certain flexibilities for providers and suppliers to account for the various circumstances that may involve an overpayment. However, providers and suppliers need to calculate an overpayment amount that is reliable and accurate, which in some cases can be accomplished using statistically valid sampling methodologies. This final rule expressly anticipates that providers and suppliers may, but are not required to, use statistical sampling and extrapolation for calculating the overpayment amount. We note that reasonable diligence requires that any statistical sampling be conducted in a manner that conforms to sound and accepted principles. These principles include randomly selecting claims from the population and extrapolating only within the time period covered by the population from which the sample was drawn.

Comment: Many commenters questioned whether the existing self-reported refund process would need to be used to report and return overpayments associated with cost reports. Commenters noted that the proposed rule does not specifically identify a separate process for cost report-related overpayments. If we intended to propose using the self-reported refund process for cost report overpayments, commenters suggested that we reconsider. Commenters stated that the voluntary refund process is not designed for providers, such as federally qualified health centers, returning overpayments identified through the cost reimbursement process, where the overpayment amount is based on the reimbursement of allowable costs, particularly where an overpayment resulted from the inclusion of costs in error or that are otherwise non-reimbursable (in which case no specific claims for payment can be identified for repayment). Requiring the use of the self-reported refund process for these overpayments would be ineffective and inefficient according to commenters. Commenters recommended we clarify that overpayments associated with cost reports be reported and returned through the existing cost reporting process.

Response: We agree with commenters and note that § 401.305(d)(1) allows for overpayments associated with cost reports to be reported through the existing cost report reconciliation process, and does not require the use of the self-reported refund process for overpayments based on cost reports. If an overpayment is identified through the initial submission of a cost report, the cost report should state that the overpayment resulted from reimbursements made at an estimated rate exceeding actual reimbursable costs and the overpayment is submitted along with the transmittal of the cost report to the contractor. Where an overpayment is identified in connection with cost-based reimbursement paid to a provider during a previous cost reporting cycle, the overpayment should be reported by amending or reopening the cost report and the overpayment should be returned by submitting payment along with the amended or reopened cost report.

Comment: A number of commenters requested creation of a materiality or de minimis exception for small-dollar overpayments from the rule. Commenters expressed concern that in many situations the cost and resources associated with reporting and refunding the overpayment would exceed the amount of the overpayment. Commenters stated that the administrative burden to process an overpayment could have a significant negative financial impact on the provider's ability to offer future services. In support of their position, commenters noted that a materiality standard is included in other areas of Medicare payment policy and related fraud and abuse enforcement policies. For example, the Medicare Financial Management Manual (MFMM) instructs Medicare contractors not to attempt recovery of overpayments under $10. (See MFMM Ch. 3, section 170.2 (Rev. 29, January 2, 2004). Similarly, under the physician self-referral law regulations, certain incidental medical staff benefits with limited value (less than $31 for 2012) are exempted. (See 42 CFR 411.357(m)). Moreover, commenters stated that CMS currently follows a materiality threshold of $300 for Medicare Secondary Payer liability recoveries. Under the CMPL, OIG stated that they may enforce the prohibition against improper remuneration to patients when the remuneration exceeds $10 for each item or $50 in the aggregate. (See the August 30, 2002 HHS OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries (67 FR 55855). Finally, in its Corporate Integrity Agreements (''CIAs''), OIG recognizes a materiality threshold by permitting the offset of underpayments to overpayments for purposes of calculating a net financial error rate, which then is used to determinate whether a sample review must be expanded to a larger review. As such, commenters requested a regulatory de minimis standard for this rule. Suggested minimum monetary thresholds ranged from $5 to $5,000. Alternatively, commenters requested CMS acknowledge that providers and suppliers can and should perform responsible cost and benefit analyses before committing resources to investigate low-dollar overpayments. Some commenters requested a minimum threshold for the voluntary refund program that permitted aggregating small-dollar overpayments identified over a period of time into one submission.

Response: We decline to adopt a minimum monetary threshold in this final rule. We believe adopting a regulatory de minimis standard would be susceptible to abuse, especially in the

context of claims-based overpayments. We also note that some of the examples provided by commenters require clarification. For example, the referenced Medicare Secondary Payer threshold relates to the size of certain liability insurance settlements, not the amount of the debt. In addition, the physician self-referral law's exception for medical staff incidental benefits of low value is not only unrelated to overpayments made to providers, but is also subject to additional program safeguards in order for the exemption to be available. With the exception of the physician self-referral law, we note that the remaining examples are detailed in subregulatory guidance, program instructions, or a negotiated contract with OIG that is applicable only to a specific party. We also disagree with commenter's request to acknowledge cost and benefit analyses before committing resources to investigating a potential overpayment. Providers and suppliers need to take reasonable steps to determine whether they have received overpayments and are required to return any funds received or retained under title XVIII of the Act to which they, after applicable reconciliation, are not entitled under such title.

Given the differences in cost report-related payments and the resources needed on both the provider and the contractor's part in the cost report process, we are considering establishing a minimum monetary threshold for cost report-related overpayments. This threshold would be published in program guidance or future rulemaking.

Comment: Some commenters requested that we exempt small-dollar overpayments from the voluntary refund process. Under the proposed rule, any overpayment would have to be reported and returned through the voluntary refund process, which requires submitting a significant amount of information. Therefore, commenters recommended establishing a minimum threshold overpayment amount under which providers can use existing claims adjustment processes to return the overpayment. Commenters offered the New York State Office of the Medicaid Inspector General (NY OMIG) as an example of a reporting process that has established a $5,000 threshold. According to the comments, if the amount of the overpayment falls below this threshold, providers are permitted to return the overpayment through existing claims adjustment processes.

Response: We decline to establish a regulatory minimum threshold amount for the voluntary refund process. However, we believe that we addressed commenters' concerns by clarifying in the final rule that providers and suppliers may use the most applicable process established by the contractor to report and return, including the claims adjustment process. We note that even under the NY OMIG process offered as an example, overpayments of any size need to be reported and returned.

Comment: Many commenters agreed with the treatment of the CMS Voluntary Self-Referral Disclosure Protocol (SRDP) and the OIG Self-Disclosure Protocol (SDP) as tolling the deadline for returning the overpayment. Commenters requested that CMS clarify that self-disclosure by providers and suppliers to other government entities, such as DOJ and MFCU, would similarly suspend the 60-day deadline.

Response: We finalized the treatment of the SRDP and SDP as tolling the obligation to return the overpayment as proposed. With regard to the SRDP, the requirement to return the overpayment within 60 days of identification is tolled for the full duration of the time that the provider or supplier is negotiating a potential settlement with CMS in accordance with the requirements of the SRDP. While engaged in the SRDP, a provider or supplier is subject to all the requirements of the SRDP, and any subsequent changes or updates to the SRDP instructions issued by CMS, independent of any similar requirements imposed by this rule. At such time that a provider or supplier is no longer actively negotiating a settlement or is not considered to be engaged in the SRDP process, the tolling will no longer be in effect and the provider or supplier is expected to comply with the 60-day returning requirements of this rule. This treatment applies to all providers and suppliers already engaged in the SRDP at the time this final rule is effective as well as those who submit a reported overpayment to the SRDP after the effective date of this rule.

We decline to extend this treatment to self-disclosure to entities outside of the SRDP and SDP in this final rule. The SRDP and SDP are both formal processes managed by agencies within the Department, CMS and OIG respectively. As such, we believe it is appropriate to include those processes in this rule. However, DOJ is a separate department and we are not aware of any formal self-disclosure process by DOJ that is analogous to the SRDP or SDP. Also, we are not aware of a similar MFCU process and, more importantly, Medicaid is not covered in this rulemaking.

Comment: Many commenters questioned treating the SRDP and SDP differently for purposes of satisfying the reporting obligation. In the proposed rule, the SDP submission satisfied the reporting obligation but the SRDP did not, which required the provider to file reports with both the overpayment refund process and the SRDP. Commenters questioned the utility of this duplicative reporting and requested that CMS eliminate it in the final rule.

Response: We agree with commenters and have revised § 401.305(d)(2) to permit the SRDP report to satisfy the reporting obligation in addition to the SDP.

Comment: A commenter requested confirmation that a provider or supplier may provide a single notification to the Department or its contractors to satisfy the report and return requirement and does not also need to use the SDP or SRDP.

Response: Providers and suppliers need to decide who is the most appropriate recipient of the overpayment report and refund as provided in § 401.305(d)—the applicable Medicare contractor, the SDP, or the SRDP. Providers and suppliers should review the SDP and SRDP to determine whether either of those avenues is available. The commenter also appears to believe that overpayments can be reported and returned to the Department, which is incorrect. Sending an overpayment report and refund to anyone other than the appropriate Medicare contractor according to the applicable administrative process (or otherwise following § 401.305(d)) does not conform to any applicable process as discussed in this final rule.

Comment: Some commenters requested guidance on when a contractor would refer an overpayment report to OIG.

Response: Medicare contractors have long been instructed to refer potential fraudulent conduct to law enforcement.

Comment: Many commenters questioned using CMS or OIG's acknowledgement of receipt of the disclosure as the action that suspends the returning deadline. Commenters expressed concern that they do not always receive this acknowledgement in a timely way. Commenters requested CMS use the date the submission was sent to CMS or OIG as the suspension date and require the provider or supplier to retain the appropriate documentation.

Response: We decline to adopt this suggestion. While we understand the concern about receiving a timely acknowledgement response, we believe that this concern does not outweigh the benefit of using the government's acknowledgement to avoid any potential

question as to whether the government actually received the submission. Self-disclosures to the SRDP must be submitted by email to *1877SRDP@cms.hhs.gov.* Parties that send their submission to *1877SRDP@cms.hhs.gov* receive a response email acknowledging receipt of the submission. This response email serves as CMS' acknowledgement of receipt. We understand that parties that send their submission through OIG's SDP online submission portal, *http://oig.hhs.gov/compliance/self-disclosure-info/index.asp,* also receive a response email. We also understand that SDP hard-copy submitters receive an acknowledgement letter from OIG confirming receipt. Either of these communications from OIG serves as the acknowledgement of receipt for purposes of this final rule.

Comment: A commenter questioned what would happen if the provider or supplier and OIG are unable to reach a settlement in the SDP. The proposed rule provided that the deadline for returning overpayments will be suspended when the 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 Self-Disclosure Protocol. The commenter requested CMS clarify that, if a settlement could not be reached through the SDP, then the provider would have a reasonable amount of time to make a report to the relevant Medicare contractor to meet its obligations under this rule.

Response: This final rule contains the same language as the proposed rule concerning the returning obligation. In the event that a SDP settlement is not reached, the provider or supplier has the balance of the 60-day time period remaining from identification to the suspension of that 60-day period when OIG acknowledged receiving the SDP submission to report and return any overpayment to the contractor. If the overpayment has been identified, we believe that the balance of the 60-day period is a reasonable amount of time to report and return the overpayment to the contractor if the SDP does not result in a settlement. We revised this final rule to clarify that the same rule would apply to a failure to reach a SRDP settlement.

Comment: A commenter requested additional exceptions from the rule or lengthier timeframes for reporting and returning overpayments based upon the size of the provider. The commenter stated that small providers and suppliers may lack the infrastructure to audit claims at the frequency required to be in compliance with the proposed rule.

Response: We decline to adopt the commenter's suggestion. The timeframe is established by the statute does not create different obligations based on provider type or size. We recognize that there is great diversity in the health care industry in provider type and size. All members of that industry who participate in the Medicare program are obligated to ensure they bill Medicare properly and to return overpayments they have received.

Comment: Several commenters objected to the 60-day deadline for reporting and returning an overpayment. Some commenters expressed concern that certain providers and suppliers might not have the resources to complete an investigation within 60 days and that CMS should establish a process for requesting an extension to the 60-day deadline. A commenter suggested that CMS adopt a process that allows the provider to report, but not to return, the overpayment within 60 days. Similarly, another commenter requested that the final rule clarify whether the obligation to report an overpayment is distinct from the obligation to return an overpayment.

Response: The 60-day deadline to report and return is contained in section 1128J(d) of the Act. We believe we addressed the concerns that underlie these comments by clarifying the provider or supplier's ability to conduct reasonable diligence and that this reasonable diligence time period of 6 months is in addition to the 60-day report and return time period, as discussed previously. We considered but declined to establish a new process for reporting, but not returning, overpayments. We believe we have addressed those comments by both the reasonable diligence clarifications and the expansion to using other processes to report and return besides the self-reported refund process.

Comment: Some commenters recommended that that 60-day timeframe for reporting and returning overpayments be reduced to 30 days. These commenters did not believe providers and suppliers should have such a long grace period to keep taxpayer money to which they are not entitled.

Response: We understand the commenters' concerns, but the 60-day deadline to report and return is contained in section 1128J(d) of the Act.

Comment: Several commenters questioned the proposed rule's use of the Extended Repayment Schedule (ERS) and requested that the definition of ''hardship'' and the documentation requirements be changed so that providers and suppliers could more easily utilize ERS. These commenters stated that the hardship standard was too difficult to meet. Commenters also requested more guidance on the documentation requirements for using the ERS. Commenters suggested changing the definition of ''hardship'' to focus on the provider's financial stability and not simply the amount of their Medicare payments and overpayments in comparison to their total Medicare billing. Some commenters suggested that the process be streamlined so that small providers and suppliers may more easily take advantage of ERS. Finally, commenters recommended that the ERS include a provision allowing for a waiver of an obligation to repay an overpayment ''if circumstances exist to merit such waiver.''

Response: We appreciate the comments. In the February 16, 2012 proposed rule (77 FR 9183), we stated that providers or suppliers who needed additional time to return the overpayment due to financial limitations should use the existing ERS process as outlined in Publication 100–06, Chapter 4 of the Financial Management Manual. We also proposed modifying the definition of ''hardship'' in § 401.607 to ensure that providers and suppliers could seek to use ERS by amending the definition to include overpayments reported in accordance with § 401.301 through § 401.305. We noted in the proposed rule (77 FR 9183) that requests for ERS are not automatically granted and that providers and suppliers seeking to use ERS must submit significant documentation to verify true financial hardship. We have added § 401.305(b)(2)(iii) in this final rule to allow for the suspending of the deadline for returning overpayments when a person requests an ERS as defined in § 401.603. Explanation of the ERS and its documentation requirements are contained in Publication 100–06, Chapter 4 of the Financial Management Manual.

Comment: A commenter stated that providers and suppliers do not have access to the same data formats and elements as the contractor. This commenter recommended that CMS create a portal with a unique provider identifier that would allow unlimited access to the National Data Repository.

Response: We appreciate the comment. Questions about data format and elements should be directed to the provider or supplier's applicable contractor. We will consider ways to

further educate providers and suppliers on these issues in the future.

Comment: Some commenters expressed concern about increasing billing errors, and consequent overpayments, when ICD–10 is implemented. These commenters recommended a grace period to accommodate these changes.

Response: We understand the commenters' concerns, but decline to adopt a grace period as suggested. It is unclear from the comments whether they are advocating for a grace period from the requirement to report and return overpayments relating to ICD–10 miscoding or an extension of the 60-day timing requirement. Regardless, we see no basis in section 1128J(d) of the Act to permit either suggestion.

III. Provisions of the Final Regulations

For the most part, this final rule incorporates the provisions of the proposed rule, with the following exceptions:

• In § 401.305 we modified our proposals as follows:

++ In paragraph(a)(1), we revised the requirements for reporting and returning of overpayments to more clearly distinguish between the concepts of receiving and identifying an overpayment. A person that has received an overpayment must report and return in the form and manner required.

++ In paragraph (a)(2), we revised the requirements for reporting and returning of overpayments slightly to remove the terms ''actual knowledge'', ''reckless disregard'', and ''deliberate ignorance'' and to state that a person has identified an overpayment when the person has or should have through the exercise of reasonable diligence determined that the person has received an overpayment and quantified the amount of the overpayment. A person should have determined that the person received an overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment.

++ Added a new paragraph (b)(2)(iii) to specify that the deadline for returning overpayments will be suspended when a person requests an extended repayment schedule as defined in § 401.603.

++ Removed proposed paragraph (d), which specified 13 specific data elements that were to be included in the report that providers and suppliers use to report and return overpayments. We subsequently renumbered paragraphs (e) through (g) as (d) through (f).

++ In paragraph (d)(1) (which was proposed paragraph (e)(1)), we revised the allowable reporting process to include an applicable claims adjustment, credit balance, self-reported refund, or other reporting process set forth by the applicable Medicare Contractor. We specified that 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.

++ In paragraph (d)(2) (which was proposed paragraph (e)(2)), we added disclosure to the CMS Voluntary Self-Referral Disclosure Protocol (SRDP) as a method of satisfying the reporting obligations for self-identified overpayments.

++ In paragraph (f) (which was proposed paragraph(g)), we revised the lookback period from 10 years to 6 years to specify that overpayments must be reported and returned only if a person identifies the overpayment within 6 years of the date the overpayment was received. We carefully considered all of the comments on the lookback period and concluded that a 6-year time period is the most appropriate time period.

• In § 405.980, we—

++ Removed proposed paragraph (b)(6). This paragraph would only apply to reopenings initiated by the contractor.

++ Added paragraph (c)(4) to clarify that a reopening may be requested under § 405.980(c).

IV. Collection of Information Requirements

A. Background

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to 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.

The following is a discussion of the provisions, as stated in section II. of this final rule, that contain information collection requirements.

B. ICR Estimates in the Proposed Rule

Proposed § 401.305 stated that a provider or supplier must (1) 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 (2) 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 was the time and effort necessary to report and return the overpayment in the manner described at § 401.305.

For purposes of § 401.305 only, we estimated 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 provisions. We estimated this based on the improper payment rate for the Medicare Fee-for-Service program, which was approximately 12 percent in FY 2014 and FY 2015,[4] and we expect that some number of improper payments will be identified by sources other than providers and suppliers themselves. We projected that each of these providers and suppliers would, on average, separately report and return approximately 3 to 5 overpayments. In addition, we estimated that it would take a provider or supplier approximately 2.5 hours to complete the applicable reporting form and return an overpayment.

We are developing an information collection request for OMB review and approval that will authorize the collection of the applicable reporting form. The public will have an opportunity to review the information collection and submit comments. We plan to announce the information collection request under the required 60-day and 30-day **Federal Register** notice and comment periods. These notices will incorporate the process described below and the burden calculated in Table 1, among other processes.

We determined that the two main categories of individuals who would most likely complete and submit the applicable reporting form included: (1) Accountants and auditors (external and in-house); and (2) miscellaneous in-house administrative personnel. Each provider's and supplier's individual operations are different and, as a result,

[4] *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/index.html?redirect=/cert.*

it was not possible to break down the percentage of total affected providers or suppliers that would fall within the 2 previously stated categories (for example, percentage of providers that would use an accountant). Consequently, in order to determine the burden cost, we utilized the average hourly wage of these 2 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'' was $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'' was $16.99 (*http://www.bls.gov/oes/current/oes433031.htm*). The average of these 2 figures, including fringe benefits and overhead, was $37.10. This lead to an aggregate annual ICR cost burden—attributable to the impacted 125,000 providers and suppliers, and using the range of 3 to 5 overpayments, of $34.78 million and $57.97 million, respectively.

C. Comments Received

We received a number of comments regarding our proposed ICR estimates:

Comment: Several commenters suggested that the burden analysis offered by CMS in the proposed rule was inadequate because it only considered two types of individuals involved in the reporting and returning of overpayments, accountants/auditors and in-house administrative personnel. Commenters suggested that additional and more costly individuals, such as legal counsel and compliance consultants, would be necessary to comply with this rule.

Response: We disagree. We believe only the rarest of circumstances (such as potential fraud or certain investigations of potential violations of the physician self-referral law) would necessitate more costly personnel, such as legal counsel, to comply with this final rule. In the overwhelming majority of cases, we expect overpayment identification and return to be sufficiently handled by accountants, auditors, and in-house administrative personnel.

Comment: Several commenters stated that CMS—(1) underestimated the administrative burden imposed by this rule; and (2) failed to adequately support the assumptions underlying the regulatory impact analysis.

Response: We understand the commenters' concerns regarding the underestimation of the administrative burden and the failure to adequately support assumptions underlying the regulatory impact analysis. Therefore, we have increased the projected ''per report'' burden—which includes researching, reporting, and returning the overpayment—from 2.5 hours to 6 hours to address these concerns. Our assumptions also include our belief that the majority of these 6 hours will be spent researching and identifying the overpayment, and that the time burden for reporting and returning the overpayment after it is identified is minimal.

D. Final Estimated ICR Burden

There are two major changes from our projected burden in the proposed rule. First, as noted previously, we are increasing the ''per report'' hour burden from 2.5 hours to 6 hours. Second, we must use more recent BLS data in calculating the hourly wage.

According to BLS information for May 2014, the national estimated mean hourly wage for the category of ''accountants and auditors'' was $35.42 (see *http://www.bls.gov/oes/current/oes132011.htm*) and the national estimated mean hourly wage for the category of ''bookkeeping, accounting, and auditing clerks'' was $18.30 (*http://www.bls.gov/oes/current/oes433031.htm*). The average of these 2 figures, is $26.86. This does not include fringe benefits and overhead which are generally calculated as being 100% of salary. This means the cost of an hour of work is $53.72.

The following table shows the projected annual ICR hour and cost burdens associated with § 401.305:

TABLE 1—ESTIMATED ICR BURDEN OF § 401.305

Number of reported and returned overpayments per affected provider	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)
3	0938—New	125,000	375,000	6	2,250,000	$53.72	$120,870,000
4	0938—New	125,000	500,000	6	3,000,000	53.72	161,160,000
5	0938—New	125,000	625,000	6	3,750,000	53.72	201,450,000

Therefore, we project an annual ICR cost burden of between $120.87 million and $201.45 million. The former represents our low-end estimate, while the latter is our high-end estimate. The $161.16 million estimate represents our primary, or mid-range, projection. While we have used a range of values to illustrate the possible burden estimates that providers may incur, we cannot submit a range of values for OMB approval. For purposes of OMB review and approval, we will use the mid-range estimate related to 4 reported and returned overpayments.

V. Regulatory Impact Statement

A. Background

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 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 Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 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 regulatory 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 rule, all stakeholders are 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 final rule imposes a new deadline on the return of any overpayment that has been identified. We believe that this change will spur providers and suppliers 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 annual burden costs for reporting and returning of overpayments, as discussed in section IV. of this final rule, are estimated between $120.87 million and $201.45 million. Since there may be years where the burden costs exceed $100 million, we believe this rule is a major rule and economically significant.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year. With a maximum cost of $201,450,000, 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. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this final rule will not have a significant economic impact on a substantial number of small entities.

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 604 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 for Medicare payment regulations and that has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined and the Secretary certifies that this final 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 of $100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately $144 million. This rule will have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it announces 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. Since this final rule does not impose any costs on states or local governments, the requirements of Executive Order 13132 are not applicable.

Comment: A commenter expressed concern that the proposed rule creates an unfunded requirement that forces medical practices to implement self-audits and internal compliance plans, and that CMS did not address this burden in the RIA.

Response: We disagree that this rule creates a requirement for any formal compliance plan or audit strategy; rather, it requires that providers and suppliers maintain responsible business practices and conduct a reasonably diligent inquiry when information indicates that an overpayment may exist.

B. Accounting Statement and Table

As required by OMB Circular A–4 (available at link *http://www.whitehouse.gov/sites/default/files/omb/assets/regulatory_matters_pdf/a-4.pdf*), we have prepared an accounting statement. The entries in Table 2 reflect the application of a 7 percent and 3 percent annualized rate to the high-end, primary, and low-end estimates referred to in section V. of this final rule. The 7 and 3 percent figures were applied over a 10-year period beginning in 2015, with the figures in the accounting statement reflecting the average annualized costs over this period.

The accounting statement does not address the potential financial benefits of this final rule from the standpoint of its effectiveness in recouping overpayments. We do not have sufficient data on which to base a monetary estimate of recovered funds. We note that the only costs associated with this final rule for providers and suppliers involve the actual researching, reporting, and returning of overpayments. For purposes of our RIA estimates, we do not deem the actual refunded overpayment as a cost since it constitutes money to which the provider or supplier was not entitled.

TABLE 2—ACCOUNTING STATEMENT: ESTIMATED COSTS RESULTING FROM REPORTING AND RETURNING OF OVERPAYMENTS

Category	Primary estimates (in $ millions)	Low estimates (in $ millions)	High estimates (in $ millions)	Year dollars	Discount rate (%)	Period covered
Costs:						
Resulting from reporting and returning of overpayments	$161.16	$120.87	$201.45	2015	7	2015-2024
	161.16	120.87	201.45	2015	3	2015-2024
Who Is Affected	Providers and Suppliers.					

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 the proposed provisions. However, we contemplated several operational mechanisms to alleviate the burden on the provider and supplier communities.

First, we proposed a new, unified form as part of the reporting and returning process in our proposed rule. However, the comments received indicated that this could cause needless additional burden. Instead, we elected to utilize existing processes for reporting and returning, including the voluntary refund process. This would allow providers and suppliers to use a reporting mechanism with which they are already familiar. After reviewing the

comments, we raised the burden to 6 hours for identifying and reporting and returning, but that is lower than if we had finalized our plan to develop a new singular form for reporting and returning.

Second, we contemplated the appropriate length of time in which overpayments must be reported and returned. A time period of 10 years was proposed, as this is the outer limit of the FCA statute of limitations. We solicited comment on this issue, and as discussed at length in section II.C.3. of this final rule, we agreed with commenters that a period of 6 years was more appropriate and will reduce the burden imposed on providers and suppliers by this final rule compared to the longer proposed lookback period of 10 years.

D. Beneficiary Access

We do not anticipate any impact on beneficiary access to care as a result of this rule. As noted previously, 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.

In accordance with the provisions of Executive Order 12866, this rule was reviewed by OMB.

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 amends 42 CFR 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, 1871, and 1874(e) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395w–5).

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

Subpart D—Reporting and Returning of Overpayments

Sec.

Subpart D—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(d) of the Act.

§ 401.303 Definitions.

For purposes of this subpart—

Medicare contractor means a Part A/Part B Medicare Administrative Contractor (A/B MAC) or a Durable Medical Equipment Medicare Administrative Contractor (DME MAC).

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 of this chapter) or a supplier (as defined in § 400.202 of this chapter).

§ 401.305 Requirements for reporting and returning of overpayments.

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

(2) A person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment.

(b) *Deadline for reporting and returning overpayments.* (1) A person who has received an 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 the following occurs:

(i) OIG acknowledges receipt of a submission to the OIG Self-Disclosure Protocol and will remain suspended 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 CMS Voluntary Self-Referral Disclosure Protocol and will remain suspended until such time as a settlement agreement is entered, the person withdraws from the CMS Voluntary Self-Referral Disclosure Protocol, or the person is removed from the CMS Voluntary Self-Referral Disclosure Protocol.

(iii) A person requests an extended repayment schedule as defined in § 401.603 and will remain suspended until such time as CMS or one of its contractors rejects the extended repayment schedule request or the provider or supplier fails to comply with the terms of the extended repayment schedule.

(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) *Reporting.* (1) A person must use an applicable claims adjustment, credit balance, self-reported refund, or other reporting process set forth by the applicable Medicare contractor to report an overpayment, except as provided in paragraph (d)(2) of this section. 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.

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

(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 31 U.S.C. 3729.

(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.

§ 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 citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 5. Section 405.980 is amended by adding paragraph (c)(4) to read as follows:

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

* * * * *

(c) * * *

(4) A party may request that a contractor reopen an initial determination for the purpose of reporting and returning an overpayment under § 401.305 of this chapter.

* * * * *

Dated: August 27, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: February 5, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

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