JONES DAY

FEBRUARY 2016

COMMENTARY

CMS Publishes Long-Awaited 60-Day Repayment Final Rule for Identified Overpayments

Four years after the initial publication of the proposed rule, the Centers for Medicare and Medicaid Services ("CMS") released the long-awaited Final Rule regarding the identification, reporting, and repayment of Medicare overpayments as required under the Affordable Care Act ("ACA"), on Friday, February 12, 2016. As the health care industry is aware, one of the program integrity measures included in that statute (and codified at 42 U.S.C. §1395k(d)) is the requirement that all Medicare overpayments be reported and returned. Once overpayments have been identified, the statute also requires that such reporting and repayment be made by the later of (i) the date that is 60 days after the date on which the overpayment was identified, or (ii) the date any corresponding cost report is due, if applicable. CMS acknowledges in the preamble that its Proposed Rule had conflated the statutory provision imposing the obligation to repay all overpayments with the provision imposing the deadline by which to repay identified overpayments, and the agency indicates that its revised language in the Final Rule is intended to decouple the two provisions.

In its February 2012 Proposed Rule, CMS addressed a number of issues relating to the identification and repayment of Medicare overpayments received by providers and suppliers. Two elements of the Proposed Rule drew the most criticism and official comment: (i) defining the term "identified" as it relates to a defined "overpayment," and (ii) proposing a 10-year look-back period and, related to that, a proposed expansion of the reopening period to 10 years. As part of this Final Rule, CMS has revised what it means to "identify" an overpayment and has scaled back the look-back period.

The first element, the definition of "identification" of an overpayment, is critical because "identification" starts the clock for the repayment deadline of 60 days or the next cost report filing and yet is not defined in the statute. CMS in the Final Rule defines "identification" to have occurred when a provider or supplier "has or should have, through the exercise of reasonable diligence, determined that [it] has received an overpayment and quantified the amount of the overpayment." This new language both imposes new obligations and provides relief to providers and suppliers, by expanding the provider's or supplier's obligation to determine when it has received an overpayment but also permitting the provider or supplier some additional time to investigate and quantify any potential overpayments before reporting and repaying.

© 2016 Jones Day. All rights reserved.

The Final Rule expands the provider's or supplier's obligations by refusing to restrict "identification" to situations where the provider or supplier has actual knowledge of an overpayment. Limiting the definition of "identification" to "actual knowledge" would, CMS states, incentivize providers and suppliers to avoid acquiring actual knowledge of an overpayment in order to avoid its repayment obligation, which CMS believes is contrary to Congress's intent.

In addition, CMS uses its "reasonable diligence" standard to expand the provider's and supplier's obligations beyond merely investigating allegations of overpayments. Consistent with its position that the statute's requirement of repaying overpayments stands independently, CMS emphasizes in the preamble that "reasonable diligence" requires "proactive compliance activities" to identify overpayments, as well as reactive investigations into "credible information of a potential overpayment."

At the same time, however, expressly permitting the provider or supplier to conclude its "reasonable diligence" before an overpayment is deemed "identified" permits providers and suppliers additional time to conduct a factual investigation and then quantify any overpayment received, before the 60-day clock begins to run. For providers that do not exercise "reasonable diligence" when confronted with credible information of a potential overpayment, however, and that did receive overpayments, the repayment clock begins to run when they first receive that "credible information."

The second and equally significant revision to the Proposed Rule is the look-back period for identifying an overpayment. Under the Final Rule, providers and suppliers are required to report and return overpayments that were made within six years of the date the overpayment was identified, whereas the Proposed Rule would have required a 10-year look-back. Consistent with this six-year look-back period, CMS also amends the reopening regulation to limit any application of the reopening rules so that such timing does not "present an obstacle or unintended loophole to compliance and enforcement."

In addition to these two significant issues, note that the Final Rule also:

- Applies only to providers and suppliers of items and services that are reimbursable under Medicare Parts A and B. Like the statute, the regulation does not apply to Medicare beneficiaries.
- Defines "overpayment" to mean any funds that a person has received or retained under Medicare Part A or B to which the person, after applicable reconciliation, is not entitled. CMS did not expand "applicable reconciliation" beyond cost reporting practices and activities.
- Clarifies that "applicable reconciliation" is the concluding event of the process through which a person identifies funds to which the person is not entitled. In the context of cost reporting, CMS confirms that the applicable reconciliation occurs when the cost report is filed. The cost report contains the provider's attestation, as of the time of filing, that all interim payments and costs have been reconciled, and any overpaid funds have been identified and returned. CMS concedes that certain events beyond the person's control may delay this reconciliation. In addition, when a provider receives updated information from CMS on the supplemental security income ratio, or knows that an outlier reconciliation will be performed, it need not identify any related overpayments until final reconciliation of the cost report. CMS also states that if post-filing overpayments are self-identified, these should be repaid within 60 days of identification.
- Upholds clarifications from the Proposed Rule that "claims related" overpayments (e.g., upcoding, medically unnecessary claims, double-billing), as opposed to those that are generally reconciled in a cost report, must still be reported and returned within 60 days of identification.
- Confirms that a provider or supplier satisfies the reporting obligations of the Final Rule by making a disclosure through the OIG's Self-Disclosure Protocol ("SDP") or the CMS Voluntary Self-Referral Disclosure Protocol ("SRDP"), and the disclosure results in a settlement using the process described in the respective protocol. The Final Rule further finalizes the SRDP and SDP as tolling the provider's or supplier's obligation to return an overpayment. In the case of the SRDP, the repayment obligation remains tolled as long as the provider or supplier is negotiating a potential settlement with CMS in accordance with the requirements of the SRDP. If negotiations end, or if the provider is otherwise no longer engaged in the SRDP process, tolling will cease.
- Confirms the agency's position that compliance with the Anti-Kickback Statute is a condition of payment, and that

CMS expects repayment of the full claim amount for any claim where payment was secured through fraud. The Final Rule also provides that when a provider or supplier has "sufficient knowledge of a kickback arrangement" to identify a resulting overpayment, the provider or supplier must report the overpayment within 60 days. CMS states that it will refer the reported overpayment and potential kickback arrangement to OIG and suspend any repayment obligation until the referred kickback matter is resolved. The agency expects that only actual parties to the kickback scheme would be required to repay the overpayment that was received by an innocent provider or supplier.

- Affirms that providers and suppliers may not delay the identification date due to financial hardship, instead requiring that requests for additional time to return overpayments be submitted through the existing Extended Repayment Schedule ("ERS") program. Requests for an ERS must be supported by "significant documentation" of "true financial hardship," and not all requests submitted to the ERS will be granted. The Final Rule amends the definition of "hardship" in § 401.607(c)(2)(i) to include specific reference to "overpayments reported in accordance with §§ 401.301 through 401.305." Explanation of the ERS and its documentation requirements are contained in Publication 100-06, Chapter 4 of the Financial Management Manual. The Final Rule also adds § 401.305(b)(2)(iii) to specify that the deadline for returning overpayments will be suspended once a person requests an ERS "until such time as CMS or one of its contractors rejects the [ERS] request or the provider or supplier fails to comply with the terms of the [ERS]."
- In a revision to the Proposed Rule, allows providers and suppliers to use a broad range of processes, including "applicable claims adjustment, credit balance, self-reported refund, or other reporting process set forth by the applicable Medicare contractor," to report and refund overpayments.
- Emphasizes that all providers and suppliers are subject to the statutory requirements of the ACA and could face potential False Claims Act or Civil Monetary Penalties Law liability and exclusion from federal health care programs for failure to report and return an overpayment, even if the conduct falls outside the scope of this Final Rule.

Potential Impact of and Considerations Related to Final Rule

CMS's commentary indicates that this Final Rule reflects its attempt to better balance the government's interest in promptly recovering Medicare overpayments against providers' and suppliers' need to be able to thoroughly investigate and quantify potential overpayments before reporting and repaying them. Nevertheless, the Final Rule leaves some loose ends. For example, with respect to overpayments that under the "reasonable diligence" requirement should have been identified by proactive compliance monitoring but were not, at what point in time would they be deemed "identified," if at all? What is "sufficient knowledge" of a kickback arrangement that would allow a provider or supplier to identify an overpayment? Does self-disclosure of an overpayment to the Department of Justice or local U.S. Attorney's Office toll the repayment deadline?

Also, as this rule applies only to providers receiving Part A and B overpayments, do the statutory repayment obligations also extend to suppliers and providers who receive oveerpayments from Part C and D contractors? In May 2014, CMS issued a separate final rulemaking that applies to overpayments received by Part C and D contractors, but that rule is silent with respect to the repayment responsibilities of providers and suppliers who received overpayments from those contractors. In connection with the may 2014 rulemaking, a number of health plans filed a suit in D.C. federal court against CMS earlier this month seeking to block its policies relating to the return of Medicare Advantage overpayments (see UnitedHealthcare Insurance Company et al. v. Burwell et al., Case Number 1:16-cv-00157 (District of Columbia)). The complaint includes allegations that the "reasonable diligence" standard establishes an obligation that is inconsistent with the enabling statute and may inappropriately result in false claims liability based on a negligence standard (id.). It is unclear the extent to which the outcome of that case may affect this Final Rule's application of the "reasonable diligence" standard.

The ultimate significance of this Final Rule may be the signaling of a heightened expectation that providers and suppliers employ robust compliance tools and resources to identify

potential overpayments both proactively and reactively, and to facilitate timely repayment. As such, stakeholders are advised to carefully review the Final Rule and examine their internal processes to ensure they have implemented ongoing compliance procedures that effectively mitigate overpayment-related risks.

At the most practical level, however, CMS offers a general roadmap to providers and suppliers who discover a potential overpayment. According to CMS, if a provider or supplier learns credible information regarding a potential Medicare overpayment, the provider or supplier should promptly and in good faith investigate whether an overpayment did occur and, if so, quantify it. The investigation should look as far back in time as the facts would indicate the problem is likely to have occurred, but arguably no further back than six years. If the investigation reveals an overpayment, the provider or supplier should quantify it (if necessary, using sampling and extrapolation) and then determine the most appropriate means of reporting and repaying it. Despite statements that CMS will not provide factual scenarios relating to "reasonable diligence" as part of its rulemaking process, CMS later suggests in its commentary that the "reasonable amount of time" for this entire process in not longer than eight months in total, barring exceptional circumstances. The failure to follow this roadmap promptly and in good faith may expose a provider or supplier to allegations of liability under the False Claims Act and Civil Monetary Penalties Statute. Depending on the complexity of the issue, enlisting outside counsel to conduct the investigation under privilege and to advise regarding self-disclosure and repayment options may be particularly valuable.

Lawyer Contacts

For further information, please contact your principal Firm representative or one of the lawyers listed below. General email messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com/contactus/.

Laura F. Laemmle-Weidenfeld
Washington
+1.202.879.3496
lweidenfeld@jonesday.com

Stephen G. Sozio
Cleveland
+1.216.586.7201
sgsozio@jonesday.com

Todd P. Kelly
Dallas
+1.214.969.5122
tkelly@jonesday.com

Heidi A. Wendel
New York
+1.212.326.8322
hwendel@jonesday.com

Kristen P. McDonald
Atlanta
+1.404.581.8498
kmcdonald@jonesday.com

Claire E. Castles
Los Angeles
+1.213.243.2629
ccastles@jonesday.com

Heather M. O'Shea
Chicago
+1.312.269.4009
hoshea@jonesday.com

Elizabeth Trende
Columbus
+1.614.281.3875
etrende@jonesday.com

Rebekah N. Plowman
Atlanta
+1.404.581.8240
rplowman@jonesday.com

Megan B. Webb
Los Angeles
+1.213.243.2757
mwebb@jonesday.com

Jones Day publications should not be construed as legal advice on any specific facts or circumstances. The contents are intended for general information purposes only and may not be quoted or referred to in any other publication or proceeding without the prior written consent of the Firm, to be given or withheld at our discretion. To request reprint permission for any of our publications, please use our "Contact Us" form, which can be found on our website at www.jonesday.com. The mailing of this publication is not intended to create, and receipt of it does not constitute, an attorney-client relationship. The views set forth herein are the personal views of the authors and do not necessarily reflect those of the Firm.