The much-anticipated proposed rule regarding the 60-day repayment of overpayment obligation was issued in proposed form by the Center for Medicare and Medicaid Services on February 16, 2012 (77 Fed. Reg. 9,179) [PDF]. If left unchanged, the proposed rule would substantially increase the burdens on providers and suppliers. Most notably, the proposed rule would create a new 10-year look-back period for overpayments. In addition, the proposed rule would create little certainty by establishing a deliberate ignorance or reckless disregard standard for conducting a reasonable investigation into allegations of potential overpayments and includes preamble language suggesting a new standard of "all deliberate speed" on internal investigations into potential overpayments. The proposed rule signifies a move toward more formality and standardization of the existing overpayment reporting process. Providers should carefully examine this proposed rule with an eye toward areas for comment prior to the April 16, 2012 close of the comment period.

Section 6402(a) of the Affordable Care Act established a new Section 1128J(d) in the Social Security Act entitled "Reporting and Returning Overpayments." Section 1128J(d) specifically requires a person who has received an overpayment to report and return the overpayment to the Secretary, State or other relevant contractor along with a written explanation of the reason for the overpayment. The report and return of the overpayment must occur by the later of (1) the date which is 60 days after the date on which the overpayment is identified; or (2) the date that any corresponding cost report is due, if applicable. The failure to make such a report and repayment creates an "obligation" for which a provider can be subject to liability under the False Claims Act, 31 U.S.C. § 3729, and under the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a(a)(10), under which the provider could be excluded from participation in Federal health care programs.

The proposed rule aims to define the parameters and process for reporting overpayments to CMS and its contractors utilizing an existing process for self-reporting overpayments through Medicare contractors. The proposed rule establishes new standards for repayments of overpayments but only for Medicare Part A and Part B providers and suppliers. CMS states that standards for Medicare Advantage, Prescription Drug Plans, and Medicaid MCOs will be addressed at a later date. Nevertheless, CMS cautions that the 60-day repayment obligation is effective even without implementing regulations.

One of the biggest burdens in the proposed rule is the imposition of a new 10-year look-back period, so that providers and suppliers must report any overpayments that are identified within 10 years from when the overpayments are received. Up to now, the reopening rules have seemed to suggest a 4 year look-back period. CMS states that this 10-year look-back period is based on the outer limit of the False Claims Act statute of limitations. A change to a 10-year look-back period is a burdensome one where providers and suppliers may have difficulties conducting investigations where documents and information regarding the claims at issue may no longer be readily available. In the rule's Regulatory Impact Statement, CMS seemed to indicate that it considered a shorter time period of 5-years, which would ease the burden on providers. However, CMS ultimately proposed 10-years to "further our interest in ensuring that overpayments are timely returned to the
Medicare Trust Fund." In addition, we note that CMS has proposed corresponding changes to the reopening rules in 42 C.F.R. § 405.980.

Critical to the determination of when a provider has an obligation to report and return an overpayment is: (1) the definition of the term "overpayment"; and (2) when such overpayment is "identified." Under the proposed rule, CMS would adopt the statutory definition of an "overpayment," which is defined as any funds that a person receives or retains under the Medicare program to which the person, after applicable reconciliation, is not entitled. Examples of such overpayments include, among other things, payments for non-covered services, payments in excess of allowed amounts, errors and non-reimbursable expenditures in cost reports, and receipt of funds from Medicare when another party is primarily liable.

With respect to cost report providers, CMS recognizes that an overpayment will not exist until after the reconciliation of interim payments with actual costs, which typically occurs at the time of the cost report submission with two limited exceptions. CMS proposes that providers will not be required to amend the cost report or calculate a change in reimbursement due to an overpayment relating to (1) the Supplemental Security Income (SSI) ratios used to calculate disproportionate share hospital (DSH) adjustment or (2) an outlier reconciliation, until the final reconciliation of the provider's cost report occurs.

CMS proposes that an overpayment will be considered "identified" if the provider has actual knowledge of the existence of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment. CMS believes that applying this standard will require providers and suppliers to exercise reasonable due diligence through self-audits, compliance checks or other research, to determine whether an overpayment exists. For example, a provider who receives information through a compliance hotline or other source that a potential overpayment exists but fails to make a reasonable inquiry to confirm whether an actual overpayment exists, could be subject to liability for knowingly retaining an overpayment because it acted in reckless disregard or deliberate ignorance of whether it received such overpayment. The rule and preamble language remain silent as to whether the actual knowledge refers to the existence of an issue or whether actual knowledge exists only when the amount of the overpayment is quantified.

Notably, in the preamble, CMS specifies that claims submitted in violation of the anti-kickback statute fail to meet the conditions of payment under the Medicare program and would constitute a false or fraudulent claim. CMS acknowledges that, in some cases, the party submitting the claim (i.e., a hospital) may be unaware of the existence of an improper arrangement (i.e., between a device manufacturer and a physician). CMS states that if a provider or supplier is unaware of the existence of a third party arrangement, then no overpayment has been "identified" and the provider has no duty to report or repay an overpayment amount. If, however, the provider or supplier "has sufficient knowledge" of the arrangement, then the provider or supplier would be required to report the overpayment under the proposed rule. The repayment obligation would be suspended and refer the matter referred to the OIG for further investigation. CMS, however, fails to specify the mechanism by which it would suspend the repayment obligation, which as discussed below, is generally required at the time of the report. CMS expects that the OIG to seek repayment from the parties to the kickback scheme, rather than an "innocent" provider or supplier reporting the overpayment. Of note, the agency does not entirely close the door for seeking repayment from the reporting provider by stating "the government may always seek repayment of claims paid that do not satisfy a condition of payment."

With respect to the reporting deadline, the CMS proposal draws a distinction between overpayments that are claims based and those which would generally be reconciled on a cost report.

For claims-based overpayments, a provider or supplier must report and return the overpayment within 60 days of identification. If the provider has actual knowledge of the overpayment, the 60-days would run from the date of such knowledge. Where, however, a provider receives information that it may have received a potential
overpayment, the provider is under an obligation to conduct a reasonable inquiry, which CMS proposes should occur with "all deliberate speed" after receiving the information. If the inquiry reveals an overpayment, the provider would then have 60-days to report and return the overpayment amount.

For overpayments that are generally reconciled on a cost report (i.e., graduate medical education payments), the provider must report the overpayment within 60 days of identification or on the date the cost report is due, which ever is later. CMS is careful to caution that cost report providers would be permitted to rely on this "later of” approach only for those payments which are reconciled on a cost report. Cost report providers cannot unnecessarily delay reporting of claims-based overpayments, which must be reported within 60 days of identification.

As expected, the proposed rule recognizes that the 60-day reporting period is tolled when a provider submits a self-disclosure to either the OIG through its Self-Disclosure Protocol or to CMS through the Self-Referral Disclosure Protocol (SRDP). The obligation to return an overpayment is suspended as of the date that CMS or OIG acknowledges the provider's acceptance into the program until such time that a settlement agreement is entered, or the provider withdraws or is removed from the protocol. Interestingly, the proposed rule draws a distinction between reporting through the OIG protocol and through the CMS protocol as to whether the provider has fulfilled its obligations under the 1128J(d) reporting requirements. With respect to the OIG Self-Disclosure Protocol, the proposed regulation recognizes that the provider would fulfill its 1128J(d) reporting requirement by making a disclosure to the OIG that results in a settlement agreement. By contrast, providers reporting through the SRDP would still be obligated to report the overpayment under the 1128J(d) reporting process set forth in the proposed rules. The basis for this distinction is not entirely clear, but CMS seeks comments regarding alternative approaches that would allow providers and suppliers to avoid making multiple reports.

Instead of developing a new process for reporting and repayment of overpayment amounts, CMS proposes that overpayments will be reported through the existing voluntary refund process as described in Chapter 4 of the Medicare Financial Management Manual. Under this process, providers and suppliers disclose overpayment amounts utilizing a form available on the Medicare contractor's website. This form requires the provider to provide identifying information (name, tax identification number, NPI, etc.) and information to identify the claim (i.e., health insurance claim number (HICN), date of service). In addition, the provider must identify:

- How the error was discovered;
- Reason for the overpayment;
- Description of the corrective action plan to ensure the error does not occur again;
- Whether the provider or supplier has a corporate integrity agreement (CIA) with the OIG or is under the OIG Self-Disclosure Protocol;
- Time frame that the problem existed and total amount of the refund; and
- If a statistical sample was used to determine the overpayment amount, a description of the statistically valid methodology.

CMS anticipates that it will eventually adopt a uniform reporting form for use by all Medicare contractors. In the meantime, however, CMS proposes that providers and suppliers use current forms available through their applicable Medicare contractor. Providers will be required to refund the amount of the overpayment at the time of the report or, if a provider needs additional time due to financial constraints, the provider can request an "Extended Repayment Schedule" (ERS) through an existing process set forth in Chapter 4 of the Medicare Financial Management Manual. CMS notes that an ERS will not be automatically granted and that providers will be required to submit significant documentation to demonstrate financial hardship.
CMS notes that on two prior occasions it proposed regulations to address the repayment of Medicare overpayments. On neither occasion were the proposed regulations finalized. These proposed rules again show the difficulty in trying to create uniform rules to cover what is frequently an individualized process. The statutory requirement of the Affordable Care Act, however, raises the stakes for establishing effective regulations.