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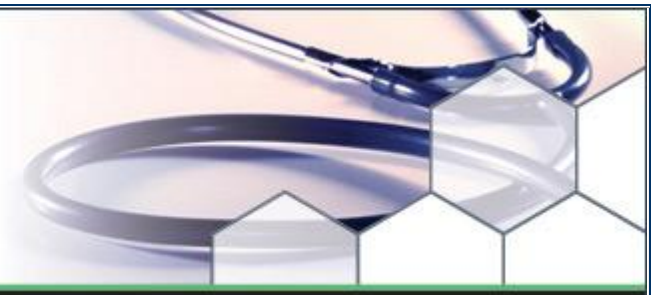

February 2016

CMS Finalizes 60-Day Rule Overpayment Regulations

On February 12, 2016, the Centers for Medicare & Medicaid Services (CMS) released a final rule (Final Rule) interpreting the application of Section 1128J(d) of the Social Security Act (the 60-Day Rule) to overpayments received under Medicare Parts A and B. The Final Rule takes effect March 14, 2016, and provides much-needed clarity on the scope and requirements of the 60-Day Rule, which has loomed over health care providers and suppliers (collectively, Providers) since its enactment in 2010 as part of the Patient Protection and Affordable Care Act.

The 60-Day Rule requires Providers that have received an overpayment to report and return the overpayment by the later of (1) 60 days after the Provider identified the overpayment or (2) the date any corresponding cost report is due. An "overpayment" includes any Medicare or Medicaid funds received that the Provider is not entitled to retain after an applicable reconciliation. Failure to report an overpayment within the 60-Day Rule's timeframe subjects a Provider to liability under the federal False Claims Act (FCA). The substantial penalties under the FCA consequently heighten the importance of 60-Day Rule compliance.

In the Final Rule, CMS most notably does the following:

- revises its proposed standard for determining when an overpayment is "identified" for purposes of the 60-Day Rule to state that an overpayment is identified when a Provider has, or should have through the exercise of reasonable diligence, determined it received an overpayment and quantified the amount of the overpayment;
- obligates Providers to conduct "reasonable diligence" to identify overpayments received, which includes both proactive and reactive 60-Day Rule compliance activities;
- adopts a six-year lookback period under which any overpayment identified within six years of the date the overpayment was received must be reported and returned; and
- generally gives Providers more flexibility in the manner in which overpayments are calculated, reported, and returned.

The question of *when* an overpayment is identified for purposes of the 60-Day Rule has prompted insecurity among Providers since 2010. In 2012, CMS issued a proposed rule regarding overpayments received under Medicare Parts A and B that stated an overpayment is identified when a Provider has actual knowledge of the overpayment or acts with reckless disregard or deliberate ignorance of the existence of the overpayment. A 2014 final rule regarding overpayments received under Medicare

Parts C and D introduced a "reasonable diligence" standard for identifying overpayments. In 2015, the first federal court to interpret the 60-Day Rule held (in the context of denying a motion to dismiss) that an overpayment is identified when a Provider is put on notice of a potential overpayment rather than the moment when an overpayment is conclusively ascertained. The heavy 60-Day Rule compliance burden endorsed by that court, combined with the differing identification standards contained in the proposed Parts A and B rule and final Parts C and D rule, as well as CMS's delay in finalizing its 60-Day Rule regulations for Parts A and B, consequently provoked significant concern among Providers about 60-Day Rule compliance and possible FCA liability tied to overpayments.

The Final Rule clarifies that a Provider has identified an overpayment when the Provider has, or should have through the exercise of reasonable diligence, determined that it received an overpayment and quantified the amount of the overpayment. As a result, the 60-day time period begins either (1) when a Provider completes reasonable diligence efforts or (2) on the day the Provider received credible information of a potential overpayment if the Provider fails to conduct reasonable diligence and the Provider in fact received an overpayment. Credible information is information supporting a reasonable belief that an overpayment may have been received, and may include but is not limited to:

- results of a contractor or government claims audit or notification by a contractor of an improper cost report payment;
- discovery of at least one overpaid claim (providing credible information of an obligation to exercise reasonable diligence to determine whether additional overpayments related to the same issue were received);
- unusually high profits from a practice or physician in relation to hours worked or wRVUs performed; or
- allegations of improper conduct.

The Final Rule's "reasonable diligence" standard requires Providers to conduct proactive compliance activities and timely investigations in response to receipt of credible information concerning a potential overpayment in good faith. A timely investigation of a potential overpayment cannot exceed six months before the 60-day time period begins—except in extraordinary circumstances—which potentially gives Providers up to eight months to exercise reasonable diligence and then report and return overpayments received. Providers may quantify overpayments through the use of statistical sampling and/or extrapolation methodologies, provided that an explanation of how an overpayment was calculated is included in the overpayment report. The Final Rule also clarifies that an overpayment consists only of the difference between the amount paid and the amount that should have been paid for an applicable claim and, for Providers that submit cost reports, that the 60-Day Rule is only implicated where a cost report error results in an increase in reimbursement.

The Final Rule adopts a six-year lookback period, pursuant to which any overpayment identified within six years of the date the overpayment was received must be reported and returned. This six-year window for reporting and returning overpayments represents a positive change for Providers from the proposed rule, which had proposed a 10-year lookback period. The Final Rule provides flexibility related to the actual reporting and returning of an overpayment by permitting Providers to return overpayments via claims adjustments, credit balances, self-reported refund processes, or another appropriate process to report and return overpayments. The Final Rule also allows CMS to suspend the deadline for returning an overpayment if a Provider requests an Extended Repayment Schedule in accordance with Medicare regulations.

As a result of the Final Rule, Providers have a duty to undertake proactive compliance activities to determine if they have received an overpayment or risk potential liability for retaining an overpayment. Providers may wish to consider implementing a process to comprehensively document all reasonable

diligence activities, as subsequent liability under the 60-Day Rule and/or FCA could turn on whether a Provider's efforts to report and return overpayments satisfy the Final Rule's reasonable diligence standard. Finally, although CMS has yet to issue or even propose regulations addressing the application of the 60-Day Rule to Medicaid overpayments, Providers are reminded that the 60-Day Rule's requirements continue to apply to Medicaid overpayments as well.

If you have any questions, please contact a member of Robinson+Cole's Health Law Group:

Lisa M. Boyle | Leslie J. Levinson | Brian D. Nichols | Theodore J. Tucci

Pamela H. Del Negro | Meaghan Mary Cooper | Nathaniel T. Arden | Conor O. Duffy

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