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The Final 60-Day Rule: the Good, the Bad, and the Ugly

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As we announced yesterday, the Centers for Medicare & Medicaid Services (CMS) has finally published the long-awaited Final Rule governing the return of Medicare Part A and Part B overpayments within 60 days (the "Final Rule"). The proposed rule, which was published nearly four years ago, led to a great deal of consternation among providers and suppliers, and thus it is no surprise that CMS received over 200 comments. The Final Rule thankfully provides a more workable approach than the proposed rule, but it demands that a provider have a proactive compliance program designed to monitor for potential overpayments and to lead to a timely investigation of credible information of receipt of an overpayment.

Compliance with the Final Rule is crucial because the potential penalties for non-compliance could be ruinous. Providers and suppliers who fail to timely identify and return overpayments face potential liability under the Civil Monetary Penalties Law as well as exclusion from the federal health care programs. In addition, under the False Claims Act (FCA), retaining an overpayment is defined as an "obligation," and "knowingly conceal[ing] or knowingly and improperly avoid[ing] or decreas[ing] an obligation" can be the basis for treble damages and penalties under the FCA.

Key Provisions of the Final Rule

Several provisions of the Final Rule will drive providers and suppliers' efforts to comply with its requirements.

1. The term "identified" requires a determination of the overpayment and—a crucial addition—"quantification" of the amount of the overpayment.

The meaning of the phrase "identified an overpayment" determines when the 60-day clock starts to run. CMS stated in the Final Rule that a provider or supplier has identified an overpayment if it: (1) "has, or ***should have*** through the exercise of ***reasonable diligence***," determined that it has received an overpayment; and (2) has quantified the amount of the overpayment. To prevent the so-called ostrich defense, CMS said in the Final Rule that providers and suppliers "should have" identified and quantified an overpayment "if the person ***fails to exercise reasonable diligence*** and the person in

fact received an overpayment."

Several aspects of CMS's definition of the term "identified" will impact how providers and suppliers must monitor, investigate, quantify, and report overpayments. For example:

- **Reasonable diligence** – According to CMS, reasonable diligence requires both proactive compliance measures (conducted in good faith by qualified individuals) to monitor for potential overpayments and timely, good-faith investigation into "credible information" of a potential overpayment.
    - CMS declined to provide specific guidance on the compliance processes required to comply with the Final Rule; instead, CMS pointed to the resources available through the Medicare Learning Network and the compliance educational material on OIG's website
    - CMS discussed that providers and suppliers can demonstrate reasonable diligence by conducting a timely, good-faith investigation into "credible information" of a possible overpayment. However, absent "extraordinary circumstances," the investigation cannot exceed 6 months. The six-month timeframe may be difficult to meet, especially given that the Final Rule requires analysis of six years of data through the six-year look-back period (discussed below).
- **Quantification and use of sampling –** The Final Rule includes quantifying the overpayment amount as a necessary part of identifying an overpayment, accounting for the difference between determining that an overpayment had been received and the auditing work necessary to quantify the overpayment amount. Moreover, the Final Rule makes clear that the overpayment amount may be determined by employing frequently used methods such as statistical sampling and extrapolation. The methodology used to quantify and overpayment must be disclosed.

2. *CMS reduced the "look back" period.*

CMS reduced the look-back period to six years. According to CMS, this timeframe is practical because it aligns with the FCA statute of limitations, and providers and suppliers commonly retain records for six to seven years based on state and federal requirements.

Providers and suppliers may be disappointed that CMS changed the look-back time period from 4 years to 6 years for overpayments based on Stark Law violations submitted through the CMS Self-Referral Disclosure Protocol (SRDP) after the Final Rule's effective date.

3. Re-opening deadlines are a one-way street.

The Final Rule amends the rules allowing for a request to a Medicare contractor to reopen initial determinations to permit reporting and returning overpayments (42 C.F.R. § 405.980(c)(4)). However, the Final Rule does not permit identification and claiming of underpayments for the same six-year period. In fact, CMS declined to allow providers and suppliers more than the current one-year period to rebill a claim to correct an identified underpayment. Moreover, the Final Rule does not allow netting of underpayments against overpayments. CMS declared that underpayment issues are outside the scope of this rulemaking.

4. Existing processes should be used to report and return overpayments.

In response to comments advocating reliance on existing processes to return overpayments, CMS allowed for the use of applicable claims adjustment, credit balance, self-reported refund, or other reporting processes established by the applicable Medicare contractor to report an overpayment. In addition, providers and suppliers, where appropriate, satisfy their 60-day reporting obligations by utilizing the disclosure processes in the OIG Self-Disclosure Protocol or the CMS SRDP, as applicable. The Final Rule includes several nuances around use of these processes, and it discusses the implications of failure to reach a settlement through either process. A provider or supplier utilizing either protocol should review carefully.

The Final Rule also removed the 13 elements of a report that CMS included in the proposed rule. For example, under the proposed rule, a report had to provide a description of how the error was identified and the reason for the overpayment. That information is no longer required by the Final Rule (but may be required by the Medicare contractor's existing processes).

5. The Final Rule includes a notable FCA discussion.

The preamble to the Final Rule also includes a notable discussion regarding the FCA. Although commenters requested confirmation that a report of an overpayment is a "public disclosure" under the FCA and therefore bars liability under the FCA's *qui tam* provisions, CMS (not surprisingly) did not respond substantively, explaining that it is interpreting Section 1128J, not the FCA.

For more details, refer to this comparison of the proposed and final rules.

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