Critical Analysis of CMS' Final Rule Implementing the Affordable Care Act's 60-Day "Report and Return" Overpayment Rule

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On February 12, 2016, the Centers for Medicare & Medicaid Services (CMS) published a long-awaited final rule (Final Rule) implementing the Affordable Care Act's (ACA's) statutory requirement that certain overpayments be reported and returned within 60 days of being identified. The Final Rule will take effect on March 14, 2016. The following critical analysis describes the Final Rule in the context of the ACA's underlying statutory requirement, contemplates legal issues implicated by the Final Rule, and raises considerations for providers and suppliers that revisit their compliance functions after the Final Rule.

The Affordable Care Act's 60-Day Rule

As the Final Rule purports to implement the ACA's statutory requirement, an analysis of the Final Rule necessarily starts with the statutory requirement, codified at 42 U.S.C. § 1320a-7k(d) (60-Day Rule). In pertinent part, the 60-Day Rule provides that "[i]f a person has received an overpayment, the person shall (A) report and return the overpayment…; and (B) notify the [entity] to whom the overpayment was returned in writing of the reason for the overpayment." The 60-Day Rule further states that "[a]n overpayment must 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." By the 60-Day Rule's plain terms, then, a person need not (indeed, *cannot*) report and return an overpayment that is neither identified nor corresponsive to a cost report.

Compliance with the 60-Day Rule is critically important to providers and suppliers because it explicitly connects its requirements to liability under the civil False Claims Act (FCA): "[a]ny overpayment retained by a person after the deadline for reporting and returning the overpayment… is an obligation (as defined [by the FCA]) for purposes of the [FCA]." The "reverse false claims" provision of the FCA, in its simplest

terms, imposes liability upon "any person who… knowingly and improperly avoids or decreases an obligation to pay or transmit money… the Government." 31 U.S.C. § 3729(a)(1)(G).

The 60-Day Rule defines only three terms: (1) "overpayment," to mean "any funds that a person receives or retains under [Medicare or Medicaid] to which the person, after applicable reconciliation, is not entitled…"; (2) "person," to mean "a provider of services, supplier, Medicaid managed care organization… Medicare Advantage organization…, or PDP sponsor…; and (3) "knowing" and "knowingly," to have the same meaning given by the FCA. The definition of "knowing" and "knowingly", however, appears to be superfluous, as the 60-Day Rule does *not* utilize these terms. In fact, this definition comes at the expense of a definition of "identified," perhaps the most critical term of the 60-Day Rule. This definitional trade is likely the result of Congress' last-minute decision to connect FCA liability *not* to the retention of "known" overpayments (as originally stated in H.R. 3962, the predecessor to the ACA), but rather to the retention of "identified" overpayments.[1]

CMS' Final Rule – Regulatory Text

The regulatory text of the Final Rule, to be codified at 42 C.F.R. § 401.301, *et seq.,* contains several important implementing provisions:

Scope of Final Rule

The Final Rule is more limited in scope than the 60-Day Rule itself, in that the Final Rule applies *only* to providers and suppliers (*not* to Medicaid MCOs, MAOs, or PDP sponsors). *See* 42 C.F.R. § 401.301. Further, the Final Rule applies only to overpayments from Medicare Parts A and B (*not* to overpayments under Medicare Parts C and D, or from Medicaid).[2] *See id*. at § 401.303 (definitions of "Overpayment" and "Person"). In 2014, CMS published a final rule implementing the 60-Day Rule with respect to certain overpayments from Medicare Part C and Part D. *See* 79 Fed. Reg. 29844 (May 23, 2014) (Parts C and D Final Rule).

Report and Return Obligation; Deadline

The Final Rule states that "[a] person that has received an overpayment must report and return the overpayment in the form and manner set forth in this section." *Id.* at § 401.305(a)(1). Nearly parroting the 60-Day Rule, the Final Rule requires that "[a] person who has received an overpayment 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* [or] (ii) the date any corresponding cost report is due, if applicable." *Id.* at § 401.305(b)(1) (emphasis added). This 60-day deadline is suspended when either the OIG or CMS acknowledges receipt of a submission into their voluntary self-disclosure protocols, or when the person requests an extended repayment schedule that is neither rejected nor complied with. *See id.* at § 401.305(b)(2).

Link to False Claims Act

Similar to the 60-Day Rule, the Final Rule states that "[a]ny overpayment retained by a person after the deadline for reporting and returning the overpayment… is an obligation for purposes of the [FCA]." *Id.* at §

[1] *See* Affordable Health Care for America Act, H.R. REP. NO. 111-3962, at 990 (2009).

[2] In the Final Rule, CMS emphasizes that overpayments from Medicaid are still subject to the statutory 60 Day Rule, even in the absence of implementing regulations.

401.305(e). As previously stated and as further discussed below, the knowing avoidance of an obligation is actionable under the reverse false claims provision of the FCA.

Form and Manner of Reporting; Exception

The Final Rule prescribes the form and manner in which an overpayment must be reported and returned, stating that "[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…." *Id.* at § 401.305(d)(1). The only exception to this requirement is for a disclosure made to *and* resulting in a settlement agreement under either the OIG's or CMS' voluntary self-disclosure protocol. *See id.* at § 401.305(d)(2).

Statistical Sampling Allowed

The Final Rule specifically allows for overpayments to be calculated on the basis of statistical sampling (despite some contractors' reticence to process such refunds), stating that "[i]f 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." *Id.* at § 401.305(d)(1).

Lookback Period Set at Six Years

The Final Rule's "lookback" provision states that an overpayment "must be reported and returned… if a person *identifies* the overpayment… within 6 years of the date the overpayment was received." *Id.* at § 401.305(f) (emphasis added).

Definition of "Identified": Reasonable Diligence and Quantification

The Final Rule's report and return obligation and lookback period both turn on the definition of "identified." As discussed and analyzed below, the Final Rule provides 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." *Id.* at § 401.305(a)(2) (emphases added). The Final Rule goes on to state that "[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." *Id.* However, the Final Rule does *not* define the phrase "reasonable diligence."

CMS' Final Rule – Analysis

Running of the 60-Day Clock

The 60-day clock begins to run either: (1) when "reasonable diligence" is completed, *i.e.,* when the provider[3] has *both* determined that an overpayment has been received *and* has quantified the overpayment; *or* (2) if the provider fails to conduct "reasonable diligence," on the day the provider received "credible information" of a potential overpayment. In either case, the provider in fact must have received an overpayment; the failure to exercise "reasonable diligence" alone, without an overpayment-in-fact, does not expose a provider to liability.

[3] The remainder of this analysis refers to "provider" to encompass both "provider" and "supplier."

"Reasonable Diligence": Proactive Monitoring and Timely Investigations

Understanding what "reasonable diligence" entails is critical, since the 60-day clock does not begin as long as reasonable diligence is ongoing. As noted above, the Final Rule does not define "reasonable diligence"; rather, CMS stated that whether "reasonable diligence" has occurred (or is occurring) will ultimately be a "fact-dependent" inquiry. 81 Fed. Reg. at 7662. At a minimum, however, "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" (emphases added). 81 Fed. Reg. at 7661. Thus, the Final Rule seeks to impose upon providers an affirmative duty to engage in "both proactive and reactive" measures regarding potential overpayments. CMS cautions that providers who undertake no, or minimal, compliance activities to monitor the accuracy and appropriateness of their Medicare claims and collections would expose themselves to liability because the 60-day clock would have ran upon receipt of credible information that an overpayment was received. According to CMS, the 60-Day Rule imposes upon providers "a clear duty to undertake proactive activities to determine if they have received an overpayment or risk potential liability for retaining such overpayments." 81 Fed. Reg. at 7664.

"Credible information"

Receipt of "credible information" triggers a provider's duty to exercise "reasonable diligence" to determine whether an overpayment was received. By adopting a "credible information" standard, which includes receipt of "information supporting a reasonable belief" that an overpayment has been received, CMS believes it has obviated the need for providers to investigate *every* single suggestion of a potential overpayment. However, determining whether a provider has received "credible information" will depend on the facts and circumstances of each particular case. To assist providers, CMS provided an illustrative (though not exhaustive) list of scenarios that could constitute "credible information." According to CMS, the following should trigger a provider's duty to exercise "reasonable diligence":

- A review of billing or payment records uncovers incorrectly coded services, resulting in increased reimbursement.
- A patient death occurred prior to the date of service on a claim that has been submitted for payment.
- Discovery that services were provided by an unlicensed or excluded individual on the provider's behalf.
- Overpayments are uncovered through an *internal* audit.
- Overpayments are uncovered through a governmental (or contractor) audit.
- There is a significant increase in Medicare revenue with no apparent reason for the increase.

See 81 Fed. Reg. at 7659. Moreover, CMS stated that the identification of even *one* overpaid claim, in and of itself, could be deemed "credible information" of the existence of *other* overpayments. CMS takes the position that "it is appropriate to inquire further to determine whether there are more overpayments on the same issue." *Id.* at 7663. Thus, *any* identified overpaid claim should spur at least some further inquiry.

CMS also stated that overpayments uncovered through a governmental audit or contractor determination *always* constitute "credible information" of potential overpayments *within* the audit period, and *may* constitute "credible information" of overpayments *outside* the audit period, *e.g.,* if there is no reason to believe conduct differed during time periods not subject to audit. *See* 81 Fed. Reg. at 7667. However, if a provider appeals an overpayment identified by a contractor, CMS notes that the provider may reasonably assess that it would be premature to engage in reasonable diligence related to potential overpayments outside the audit period, until the appeal has been resolved through the administrative process. *Id.* at 7667. Providers will need to review the specific facts and circumstances, including audit practices and

billing and coverage rules, to determine the scope of "credible information" received from results of an audit, and thus the scope of the required "reasonable diligence" to follow. Although not expressly stated by CMS, it is possible that the same analysis would apply for *internal*, non-government audits.

The Outer Boundary: Six Months

The Final Rule is clear: as long as reasonable diligence is ongoing, the 60-day clock does not start. However, that does not mean that "reasonable diligence" can occur *ad infinitum*. To encourage providers to "prioritize these investigations," CMS stated that reasonable diligence should conclude "*at most 6 months* from the receipt of the credible information, except in extraordinary circumstances" (emphasis added). 81 Fed. Reg. at 7662. Practically, that gives providers no more than eight months (absent extraordinary circumstances) to fulfill their obligations under the Final Rule—six months to conduct and conclude reasonable diligence (including quantification of the overpayment) and two months to report and return an identified overpayment.

CMS acknowledged that "extraordinary circumstances" will justify a longer period of time to conduct reasonable diligence, based on the specific facts and circumstances. *Id.* at 7662. CMS specifically noted that "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)."[4] *Id.* at 7662.

Quantification a Necessary Part of "Identification"

Agreeing with the sentiment of much of the provider community, CMS stated that *actual quantification* of an overpayment amount is necessary before an overpayment can be "identified," and thus reported and returned. As stated above, the Final Rule defines "identified" to specifically include quantification. Before the Final Rule, providers had argued, without assurance, that the final act of discerning an overpayment—quantification—was necessary before the overpayment could be deemed "identified." Providers can now be sure that they will be insulated from liability for not reporting and returning potential overpayments because they have not yet completed—within the bounds of reasonable diligence—the quantification process. Moreover, the Final Rule explicitly permits the use of statistical sampling and extrapolation to quantify an overpayment with a reasonable degree of certainty. Allaying other potential concerns related to the use of sampling and extrapolation, the Final Rule also states that "the provider or supplier should not report or return overpayments on specific claims from the probe sample until the full overpayment is identified." 81 Fed. Reg. at 7664.

Form and Manner of Reporting

Permissible Reporting Vehicles

The Final Rule establishes the processes necessary to properly report and return overpayments: either through a Medicare contractor's voluntary refund, applicable claims adjustment, credit balance, or other reporting process, or through the OIG's Self-Disclosure Protocol or CMS' Self-Referral Disclosure Protocol. A submission to either the OIG or CMS protocols satisfies the reporting obligation *only* if the submission results in a settlement agreement with the OIG or CMS. Accordingly, a failure to reach settlement with the OIG or CMS—whether through withdrawal or removal from the respective protocol—would mean that the underlying overpayments would not have been timely reported. CMS declined to acknowledge voluntary

[4] Investigations that take longer than six months and result in a conclusion that the Stark Law was *not* violated are *not* actionable under the Final Rule because no overpayment would have been determined to exist.

disclosures to other government agencies (such as the Department of Justice or Medicaid Fraud Control Units) as sufficient reports for purposes of the Final Rule. *See* 81 Fed. Reg. at 7678. The Final Rule also explains that overpayments associated with cost reports may be reported through the existing cost report reconciliation process, rather than through the self-reported refund process for overpayments. *See id*. at 7677.

Data to Include in the Report

Although the 60-Day Rule requires that providers report the *reason* for the overpayment, the Final Rule does not specify the level of detail with which a provider must describe this reason. CMS' decision to rely on existing Medicare contractors' reporting processes strongly implies that the level of detail currently required by contractors will suffice for reporting the *reason* for the overpayment. In fact, the claims adjustment processes use adjustment reason codes to describe the reason for the initial overpayment. If use of a code provides sufficient specificity about the reason for an overpayment, the Final Rule cannot reasonably be read as requiring much if any greater detail in reporting the reason for an overpayment returned through another process.

The Final Rule does require, however, 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." 81 Fed. Reg. at 7676. Acknowledging that many Medicare contractors' forms do not accommodate extrapolated refund amounts, CMS states that providers "should make a good faith effort to provide the information [about sampling methodology] 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 claims in an extrapolation." *Id.* at 7676. CMS further stated that "reasonable diligence" requires a sampling and extrapolation methodology to conform "to sound and accepted principles." *Id.* at 7677.

With respect to claims-specific refunds, CMS specifically approved the process of submitting a single refund form to a contractor with an attached spreadsheet containing appropriate data. *Id.* at 7676. CMS also noted that providers will continue to be allowed to request that a contractor accept payment through a voluntary offset. *Id*. at 7675. CMS does not intend to create a standardized refund form, but rather will work with Medicare contractors to adjust their current forms and instructions, as necessary, and will consider creating a standardized form in the future. *Id*. at 7676.

Effect of Returning an Overpayment

In preamble commentary, CMS addressed the effect of erroneously reported and returned overpayments. CMS stated that a claims-specific refund constitutes a "revised initial determination" of the subject claim(s), such that the refunding provider will have appeal rights related to that determination. *See* 81 Fed. Reg. at 7668. However, a refund that is *not* claims-specific, *e.g*., a refund resulting from statistical sampling, will *not* be considered a "revised initial determination" of any claim, and thus will not be afforded appeal rights. *Id*. at 7668. CMS indicated, though, that a provider could utilize Medicare's reopening regulations to request a correction of a mistakenly reported and returned overpayment.

More specifically, CMS stated that when a provider reports and returns claims-specific overpayments, the Medicare contractor can adjust those claims. When the refund amount is the result of extrapolation, however, CMS merely encourages providers to keep documentation of the extrapolation to present to the Medicare contractor upon audit, if necessary. CMS notes that "[w]hile 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." 81 Fed. Reg. at 7667.

CMS' Final Rule: Troubling and Unresolved Issues

Is it Reasonable for CMS to Interpret the 60-Day Rule as Imposing an Affirmative Duty to Engage in "Reasonable Diligence"?

Source of Affirmative Duty

The plain text of the 60-Day Rule does *not* expressly create any affirmative duty to monitor for overpayments; rather, it provides only that providers must report and return any overpayments within 60 days of the date such overpayments are "identified." CMS' regulatory definition of "identified," *i.e*., to require the engagement in "reasonable diligence", however, effectively creates an affirmative duty in the law. Specifically, under the Final Rule, an overpayment is "identified" when a person has received an overpayment and either (1) determined that the person has received the overpayment and quantified the amount of the overpayment or (2) *failed to exercise* reasonable diligence to determine the existence of or quantify the overpayment. Thus, an overpayment may be deemed "identified" not only upon a provider's actual discovery of the overpayment, but also if a provider should have identified the overpayment through reasonable diligence but failed to do so. In other words, CMS interprets Congress' choice of the word "identified" to encompass overpayments that are literally *un*identified. Because CMS has defined an "identified" overpayment to include not only overpayments of which providers have actual knowledge, but also certain overpayments that providers fail to discover, a provider that does not engage in reasonably diligent proactive compliance efforts greatly risks liability related to the retention of any overpayments.

CMS' Justification for Imposing an Affirmative Duty

CMS provides two justifications for its definition of "identified." *See* 81 Fed. Reg. at 7659. First, it argues that the statute's definitions of "knowing" and "knowingly", *i.e*., to include acts in deliberate ignorance or reckless disregard of the truth or falsity of information, were intended by Congress to incorporate into the 60-Day Rule a standard beyond actual knowledge. Although neither of these defined terms actually appears in the operative text of the 60 Day Rule, which requires the report and return of an "identified" overpayment, not a "known" overpayment, CMS asserts that Congress' inclusion of the definitions is evidence of Congressional intent to provide for a broad application of the 60-Day Rule to encompass both actually known and recklessly disregarded or deliberately ignored overpayments. CMS believes that, by imposing a duty to engage in "reasonable diligence," its definition of "identified" carries out this Congressional intent.

CMS also relies on a policy justification for its definition of "identified," arguing that an actual knowledge standard would discourage proactive compliance efforts and allow providers to improperly retain overpayments simply by avoiding any effort to look for them. CMS believes that Congress would not have intended these negative policy effects and that, therefore, it is justified in interpreting "identified" to actively prevent them.

Flaws In CMS' Interpretation and Justification

CMS acknowledges that neither of the terms on which it relies to interpret the 60-Day Rule as imposing an affirmative duty to monitor for overpayments—"knowing" and "knowingly"—is actually used in the operative text of the 60 Day Rule itself. *See* 81 Fed. Reg. at 7659. In fact, the plain meaning of "identified," to have established or indicated what something is, lends itself more to an actual knowledge standard. Perhaps if

Congress had chosen to use the phrase "identified or identifi*able*," CMS' interpretation would have been reasonable. Therefore, although CMS claims that its definition of "identified" carries out Congressional intent, this claim is not readily apparent from the words that Congress *actually chose* in drafting the 60-Day Rule.

Further, although CMS notes that an earlier House version of the ACA used the term "knows" rather than "identified", it does nothing to grapple with the implications of this legislative history.[5] *See* 81 Fed. Reg. at 7660. The most obvious interpretation of this legislative choice of words is that Congress explicitly rejected the 'knows or should have known' standard, in favor of an actual knowledge standard expressed through the use of the term "identified." In fact, Congress clearly and explicitly implemented a 'knows or should have known' standard in many other instances throughout the ACA (e.g., "knows (or reasonably should have known)"; "knew, or should have known through the exercise of due diligence"; "neither knew, nor exercising reasonable diligence would have known").[6] Similarly, Congress deliberately used the term "identified" in over one hundred instances in the ACA; yet not one of these instances involves a standard that could reasonably be interpreted as extending beyond actual knowledge.

CMS' definition of "identified," therefore, ignores its plain meaning, its statutory context, and the legislative history of the ACA. Although CMS presents its definition as based on Congressional intent, it does little to support this view, relying on bald assertions about Congress' purpose in including the "knowing" and "knowingly" definitions and Congress' policy preferences, and does nothing to meaningfully address the contrary evidence of Congressional intent presented by commenters. Therefore, should the Final Rule's definition of "identified" come under judicial scrutiny, it may well fail both steps of the test set forth in *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc*., 467 U.S. 837 (1984), i.e., for whether an agency's statutory interpretation is entitled to judicial deference. Specifically, the definition neither aligns with Congress' clear meaning nor is based on a "reasonable explanation of how an agency's interpretation serves the statute's objectives." *Northpoint Tech., Ltd. v. FCC*, 412 F.3d 145, 151 (D.C. Cir. 2005).

In fact, active litigation in the context of CMS' Parts C and D Final Rule (implementing the 60-Day Rule for Medicare Parts C and D) challenges CMS' interpretation of "identified" in *that* rule as extending its meaning beyond actual knowledge. A complaint filed on January 29, 2016 by UnitedHealthcare alleges that CMS' definition both conflicts with the plain meaning of the statute and is an unreasonable interpretation of an ambiguous provision. The resolution of this litigation should have important implications for the viability of CMS' similar definition of "identified" adopted in the Final Rule.[7]

[5] *See, e.g. Russello v. U.S.,* 464 U.S. 16, 23-24 (1983) (examining the evolution of the statutory provisions at issue and finding that where Congress deleted language included in an earlier version of a bill prior to enactment, it may be presumed that the language was not intended); *see also Council for Urological Interests*, 467 U.S. at 223 (refusing to refer to CMS' statutory interpretation where the agency's commentary was "plainly not a reasonable attempt to grapple with the Conference Report.").

[6] *See Russello*, 464 U.S. at 23 ("…where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (internal citation and quotations omitted).

[7] While CMS defines "identified" in the Parts C and D Final Rule using the same "reasonable diligence" language and incorporating the same negligence standard that it adopts in the Final Rule, there is an important difference between the definitions in the two rules. Specifically, in commentary to the Parts C and D Final Rule, CMS specifically stated that "[a]n organization can identify or assess that there is a problem with data submitted to CMS, and determine that it is incorrect data, *prior to actually calculating what the payment impact is of that erroneous data*." 79 Fed. Reg. 29844, 29921 (May 23, 2014) (emphasis added). The date that data is determined to be incorrect starts the 60-day clock, even if the payment impact has not yet been quantified. This dissonance between the Parts C and D Final Rule's definition and the Final Rule's definition, which provides that an overpayment is not identified until it is *quantified* (unless it is deemed identified based on lack of reasonable diligence), is not explained or justified anywhere in the Final Rule.

Did CMS Conflate the 60-Day Rule with the False Claims Act?

Troublingly, CMS' definition of "identified" seems to conflate the 60-Day Rule's report and return obligation with the FCA's reverse false claims provision, which, in pertinent part, imposes liability on anyone who "knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." The ACA makes the retention of an overpayment past the 60-day deadline an "obligation" for purposes of this provision. Because the Final Rule defines "identified" to include a failure to engage in "reasonable diligence," and because the FCA similarly defines "knowingly" to include acts in deliberate ignorance or reckless disregard of the truth, the Final Rule's standard and the FCA's standard are effectively the same—the reckless disregard or deliberate ignorance of the retention of an overpayment for more than 60 days violates the Final Rule and the FCA in equal fashion. As such, the Final Rule's definition of "identified" effectively converts every overpayment retained in the absence of a sufficiently robust compliance program into actionable FCA conduct, radically expanding potential liability associated with mere compliance failures.

Unclear Effect on Previously Returned Overpayments

Prior to the Final Rule, many providers had routinely reported and returned identified overpayments with reference to Medicare's 4-year administrative reopening window. In fact, CMS' Self-Referral Disclosure Protocol requires a 4-year lookback period in reliance on the 4-year administrative reopening window. However, based on the FCA's 6-year statute of limitations and the fact that CMS learned anecdotally that many providers retain records and claims data for six to seven years, the Final Rule imposes a longer, 6-year lookback period. *See* 81 Fed. Reg. at 7671-72. The Final Rule's adoption of this 6-year lookback raises a question: does a previous identification (and subsequent report and return) of four years' worth of overpayments constitute "credible information" of potentially similar overpayments in years 5 and 6, *i.e.,* the two years directly preceding Medicare's 4-year administrative reopening window? Without specifically addressing this question, CMS stated that providers "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 60-Day Rule] are not expected to have complied with each provision of the Final Rule." Id. at 7673. With respect to the SRDP, in particular, CMS stated that providers "that made a good faith effort to comply with [the 60-Day Rule] 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" *Id.* at 7673 (emphasis added).

Effect on Submissions to Self-Referral Disclosure Protocol

CMS has sought authorization from the OMB to collect information regarding overpayments submitted to the SRDP with a 6-year lookback period, instead of the 4-year lookback period. *See id.* at 7673. Until such approval, providers need only provide financial information according to the currently approved 4-year lookback period. However, CMS indicated that providers may voluntarily provide financial information from the 5th and 6th years, and it would be wise to do so, as if providers choose *not* to do so, they must "report and return overpayments from the fifth and sixth years through other means," *i.e.,* without the benefits afforded by the SRDP. *Id.* at 7673.

When Does the Six-Year Lookback Period Begin?

CMS explains that "the 6-year lookback period will be measured back from the date the person identifies the overpayment." 81 Fed. Reg. at 7671. However, in practice it is very difficult to pinpoint a date of "identification," and thus pinpoint a date to look back to. Based on the Final Rule's definition of "identified," the lookback period would seem to end on the date on which an overpayment is quantified, in which case the provider would need to conduct reasonable diligence as to the existence of other potential

overpayments within the six years back prior to that date of actual quantification. Providers may then grapple with when quantification should be considered sufficiently *complete*, for purposes of "identification" and pinpointing the lookback period. Does a provider look back six years from the date on which an overpayment is *initially* quantified? Most quantifications are reviewed, double-checked, and confirmed for accuracy. Does a provider look back six years from the date on which the quantification of an overpayment is finally confirmed as accurate?

What of Overpayments Resulting from "Downstream" Kickbacks?

CMS specifically addressed inquiries from providers who identify collections "resulting from" conduct that violated the Federal health care program anti-kickback statute but to which the provider was not a party. For example, what should a hospital do if it identifies Medicare collections for an item (*e.g.*, a hip replacement device) that it provided to a Medicare beneficiary as a result of a "downstream" kickback between an orthopedic surgeon and the device manufacturer? CMS indicated in preamble commentary that, in such a situation, the hospital should report the overpayment but not return it. Rather, CMS stated that it "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…. 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…." 81 Fed. Reg. at 7659.

Conflict with Prior 60-Day Rule Jurisprudence

CMS' Final Rule is directly at odds with the August 3, 2015 decision in *U.S. ex rel Kane v. Healthfirst, Inc., et al.*, Case No. 1:11-cv-2325 (S.D.N.Y.), decided before there was any proper guidance from CMS. In *Kane,* the Court adopted the Department of Justice's litigation position that, for purposes of the 60-Day Rule, "identification" occurs the moment that a provider is "put on notice that a certain claim may have been overpaid," even where "the precise amount [of the overpayment] has yet to be determined." Thus, under the *Kane* Court's interpretation of the 60-Day Rule, the 60-day clock may begin (and even run completely) before the provider has sufficient time to complete a reasonable investigation, let alone quantify an overpayment. Nonetheless, the *Kane* Court warned enforcement agencies against applying the 60-Day Rule too aggressively, implicitly approving of providers that work with reasonable diligence to identify, report, and return overpayments: "prosecutorial discretion would counsel against the institution of enforcement actions aimed at well-intentioned health care providers working with reasonable haste to address erroneous overpayments… [as] unlikely to succeed." However, it is not clear if the Final Rule will be of great utility to the defendants in *Kane*: the events that put defendants "on notice" of potential overpayments in Kane were such[8] that the defendants may have faced the same result under the Final Rule.[9]

[8] Defendant Continuum Health Partners was initially contacted by the New York State Comptroller notifying it about specific claim errors. Defendants subsequently confirmed that there was indeed a coding issue caused by a software glitch, which resulted in potential overpayments. The relator in that case, tasked with investigating the issue, identified a list of 900 potentially affected claims that he emailed to his superiors. According to the complaint, the relator was fired shortly thereafter and Continuum then "did nothing" to investigate the claims. The defendants allegedly refunded only a small number of claims over the course of two years, the majority only after the issuance of a Civil Investigative Demand.

[9] *Kane* involved Medicaid payments, whereas the Final Rule only applies to Medicare Parts A and B overpayments.

Considerations for Providers and Suppliers

Monitoring for Information that May Lead to a Report and Return Obligation

Ensuring that Information Suggesting Receipt of an Overpayment is Effectively Communicated to or within the Organization

The Final Rule is clear that "reasonable diligence" includes "investigations conducted in good faith and in a timely manner by qualified individuals in response to obtaining *credible information* of a potential overpayment." 81 Fed. Reg. at 7661 (emphasis added). Further, when queried as to the level of employee knowledge that CMS would attribute to an employer, CMS stated that "organizations are responsible for the activities of their employees and agents *at all levels*." *Id.* at 7665 (emphasis added). Therefore, although different approaches to compliance are acceptable for different sizes and types of providers, it is critical for all providers that information regarding the potential receipt of an overpayment—whether obtained by a provider's employee or agent—is communicated to the right people within the organization, so that the provider can then evaluate whether the information is sufficiently "credible" to trigger the duty to engage in reasonable diligence.

Providers, therefore, may wish to consider adopting appropriate mechanisms to facilitate such communication by employees within their organizations. In addition to maintaining open lines of communication to responsible individuals within the organization, and creating a culture wherein expressions of concerns about compliance and receipt of overpayments are valued, providers may consider implementing training programs to help employees (1) recognize information as signaling the receipt of a potential overpayment, and (2) communicate that information accurately and appropriately to the correct individuals. Such educational initiatives might be more appropriate for those employees who are most likely to receive such information, *e.g.,* coders, billers, and certain clinicians. The type of education appropriate for each type of employee may differ. Additionally, providers may wish to consider requiring employees to certify periodically that they are not aware of any information leading them to believe that the provider is in receipt of a potential overpayment or, if they are, to present that information.

Similarly, the Final Rule is clear that "[p]roviders and suppliers are responsible for the actions of their agents, including third party billing companies." *Id.* at 7666. Therefore, providers may wish to consider similar mechanisms for educating their third party agents, both as to ways to identify and monitor for information suggesting the receipt of a potential overpayment *and* as to how to communicate such information to the appropriate individuals at the provider. Further, providers may wish to consider contractual provisions requiring those agents to monitor for and report information suggesting the receipt of potential overpayments, as well as to certify periodically that they are not aware of information that the provider has received overpayments.

The provider may wish to require its employees and agents to communicate *any* information suggesting receipt of an overpayment, leaving for itself—*i.e.,* its own qualified individuals, whether compliance officers, in-house legal counsel, and/or external counsel—the duty to assess whether the information is in fact "credible" and, if so, to engage in "reasonable diligence." Regardless, providers may wish to consider periodically auditing its employees' and contractors' ability to appropriately recognize and communicate information about the receipt of a potential overpayment. Such activities might include reviewing samples of hotline tips received, the appropriateness of employee and agent responses to overpayments identified through other mechanisms (such as a government or internal audit), and sampling claims submitted by third party billing companies for potential compliance concerns.

Monitoring for Clarifications to the Law

In what will undoubtedly cause great consternation, CMS indicates that providers must not only monitor for *factual* information suggesting receipt of an overpayment, but also monitor for legal information suggesting receipt of an overpayment. Specifically, CMS stated that "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." 81 Fed. Reg. at 7658 (emphasis added). Because "clarifications" operate to *clarify*, rather than to *change*, the law that was in effect when past payments were made, such clarifications to law could have the effect of converting a payment that a provider might have reasonably *not* identified as a potential overpayment at the time it was received (or at any time prior to the clarification) into an overpayment that the provider could, as a consequence of the clarification, reasonably identify as a potential overpayment, thus triggering a duty to engage in reasonable diligence. Providers, therefore, should more carefully monitor legal guidance that constitutes a *clarification* to the law, as it may implicate not only future payments, but also historical payments.

Establishing Policies, Procedures, and Processes for Effectuating "Reasonable Diligence"

One of the most important takeaways from the Final Rule is that, once a provider learns of credible information that a potential overpayment has been received, the 60-day clock will *not* commence as long as the provider is engaged in "reasonable diligence" to both determine that an overpayment in fact has been received and quantify that overpayment. Therefore, providers may wish to consider revisiting and/or implementing policies, procedures, and processes that will help ensure that the appropriate individuals are involved and that "reasonable diligence" commences and continues until the matter is resolved. These processes may include template, written plans of action regarding how information—whether factual or legal—will be ascertained, assessed, and reviewed; prescribed timelines of when certain investigative or review activities should occur; when and how to include the appropriate internal and external resources, particularly in regard to determining the appropriate lookback period, determining the scope of an investigation of intentional conduct, and conducting a statistically valid review and extrapolation; periodic meetings to ensure that responsible parties and individuals are accomplishing their tasks; suspension of claims activity, when appropriate; and familiarity with Medicare contractors' refund processes. When crafting policies, providers should bear in mind that, under the Final Rule, *all* investigatory activities must be completed within a six-month timeframe. Moreover, the Final Rule requires the use of "qualified individuals" throughout the period of reasonable diligence; although there is not a one-size-fits-all formula for all diligent reviews, providers may wish to consider the defensibility of relying, in good faith, on objective, independent and expert third parties that are able to adhere to and attest to their own, industry-specific 'standards of care': clinical reviewers, coders, statisticians, and counsel.

Once a review or investigation commences, it would be wise to heed CMS' statement that it is "certainly advisable" to document, for posterity, all acts of reasonable diligence in determining and quantifying an overpayment. Good documentation practices will not only help ensure that "reasonable diligence" continues, but will also serve to defend any real-time or subsequent assertions that reasonable diligence has not occurred. Basic documentation practices might include the centralized preservation of time-stamped documents that show when a potential problem emerged, what the initial response was, who was involved in the review or investigation, what their activities were, when they occurred, and when efforts to quantify any overpayments were engaged in and completed.

Forecast

Given the few and relaxed elements of a reverse FCA action—mere 'knowing' 'avoidance' of an 'obligation' gives rise to treble damages and severe penalties—it is likely that a greater share of future *qui tam* FCA

actions will rely on theories of improper retention of overpayments. The Final Rule, by defining "identified" in a manner that embraces the exercise of "reasonable diligence," is fodder for whistleblowers who would claim that providers are simply not acting fast enough, or thoroughly enough, or simply don't have the infrastructure to do so at all, in response to information that an overpayment has been received. Unless and until CMS' Final Rule is challenged, providers can proactively work to minimize the legal and resource risks that such actions pose by adopting, adhering to, and instilling practices that monitor for information suggesting the receipt of an overpayment, diligently address such information when it is received, to the point of resolution, and document those efforts.

If you have any questions about the content of this advisory please contact the Pillsbury attorney with whom you regularly work, or the authors below.

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