No change under the Health Reform law has caused greater disruption to healthcare compliance and financial operations of healthcare plans and providers than the so-called “60-Day Rule.” The rule, generally requiring reporting and refunding overpayments within 60 days of identification, sounded simple enough, but uncertainty about how to implement it has resulted in compliance departments pushing everything else on their work plans to backburners. The reason for this likely unintended consequence is the perception of draconian punishments (False Claims Act (FCA) damages, Medicare and Medicaid exclusion, and civil money penalties) looming for organizations that are unable to respond immediately to the often complex and confusing landscape of Medicare and Medicaid compliance. The 60-Day Rule strikes broadly. By its terms, it is applicable not only to providers and suppliers, but also to Medicare Advantage plans, Medicare prescription drug (PDP) plan sponsors, and Medicaid managed care plans. The lack of regulatory guidance that could provide some practical and manageable approaches for dealing with the 60-Day Rule has further fueled industry concerns that the most aggressive public interpretations will be perceived as correct. This article describes the technical requirements of the new 60-Day Rule, surveys how leading organizations are applying it today, and proposes a workable solution for plans and providers seeking to apply and live with this change in the law.

**Background on Treatment of Overpayments**

There is a long history of disagreement between the healthcare bar, regulators, prosecutors, and the industry itself as to the duty to disclose overpayments innocently received and the application of the so-called “reverse false claims” theory. Historically, some providers argued there was no duty to refund innocent overpayments, once discovered. The government strenuously disagreed and cited a number of authorities for the opposite position. Qui tam cases and settlements on the theory of the “reverse false claim” (the situation where an obligation to pay or transmit money to the government is fraudulently evaded) are not of recent origin.
The FCA also has long contained a provision for “reduced damages” (reduced to double damages) for potential FCA violations that were promptly self-disclosed.4 This reduction is available if a court finds that:

- (A) the violator furnished the government “all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;
- (B) such person fully cooperated with any Government investigation of such violation; and
- (C) at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation.5

This provision was designed, however, to encourage the self-disclosure of FCA violations, not mere overpayments.

2009 and 2010 Changes to the False Claims Act and Related Authorities

2009 FERA Amendments

The law on the treatment of overpayments has evolved rapidly over the past two years. The first significant change occurred with the May 20, 2009 Fraud Enforcement and Recovery Act (FERA).6 FERA amended the FCA to indicate that entities that improperly retain overpayments from the government are liable under the FCA. 31 U.S.C. § 3729(a)(7) was replaced by Section 3729(a)(1)(G), which imposes liability if a person “knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” Although “improperly” is not defined, the FERA amendments added the following definition of “obligation” in Section 3729(b)(3): “an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor/licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment . . . .”

Under the revised Section 3729(a)(1)(G), FCA liability can exist even when there is no false claim, record, or statement submitted to the government (or a government contractor or grantee). The legislative history explains the intent behind the law: “the violation of the FCA for receiving an overpayment may occur once an overpayment is knowingly and improperly retained, without notice to the Government about the overpayment.”7 It is also important to note that Congress did not intend to disrupt the underlying regulatory structure and requirements regarding overpayments. The Senate Report confirms retentions of overpayments that are permitted by regulatory or statutory processes for reconciliation (referencing cost reports in particular) do not violate the FCA, provided such retention is not based on any willful act of the recipient to increase its payments from the government or a “scheme created to intentionally defraud the Government by receiving overpayments, even if within the statutory or regulatory window for reconciliation.”8 This perspective is important in the context of the underlying Medicare and Medicaid jurisprudence, including the “without fault” and other provisions that protect providers from liability in some contexts. The “without fault” rule reduces the risk of a provider or supplier from liability for an overpayment if it exercised reasonable care in billing for, and accepting, the payment; i.e.,

- It made full disclosure of all material facts; and
- On the basis of the information available to it, including, but not limited to, the Medicare instructions and regulations, it had a reasonable basis for assuming that the payment was correct, or, if it had reason to question the payment; it promptly brought the question to the FI or carrier’s attention.9

While the FERA amendments for the first time ensconced the “reverse false claims” theory in the FCA’s applicability to Medicare and Medicaid liability under the Social Security Act (SSA), it provided no instruction to providers (or anyone else) on the underlying duty to disclose or refund overpayments.

2010 PPACA Changes

Congress completed its amendments relating to overpayment in several sections of the March 23, 2010 federal health reform law, the Patient Protection and Affordable Care Act (PPACA).10 PPACA included the following three interrelated provisions:

1. PPACA Section 6402(d) creating a FCA “obligation,” including the express duty to refund and report Medicare and Medicaid overpayments by the later of 60 days after overpayment is “identified” or the date the corresponding cost report is due. Failure to report and return is an “obligation” for the purpose of FCA;11

2. Civil Monetary Penalties (CMP) Law provision, permitting CMPs for failing to report and return known overpayment within 60 days or when the cost report is due;12 and

3. Medicaid program exclusion authority.13

These are the provisions that will be discussed in greater detail herein, with particular attention to the provisions of PPACA Section 6402(d), which reads as follows:

“(d) REPORTING AND RETURNING OF OVERPAYMENTS.—

“(1) IN GENERAL.—If a person has received an overpayment, the person shall—

“(A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and

“(B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.
In practice, the most challenging issue for plans and providers as a result of the changes in PPACA Section 6402 is knowing when the 60-day clock has started running.

“(2) DEADLINE FOR REPORTING AND RETURNING OVERPAYMENTS.—An overpayment must be reported and returned under paragraph (1) 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.

“(3) ENFORCEMENT.—Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31, United States Code) for purposes of section 3729 of such title.

“(4) DEFINITIONS.—In this subsection:
“(A) KNOWING AND KNOWINGLY.—The terms ‘knowing’ and ‘knowingly’ have the meaning given those terms in section 3729(b) of title 31, United States Code.
“(B) OVERPAYMENT.—The term “overpayment” means any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.
“(C) PERSON.—
“(i) IN GENERAL.—The term ‘person’ means a provider of services, supplier, medicaid managed care organization (as defined in section 1903(m)(1)(A)), Medicare Advantage organization (as defined in section 1859(a)(1)), or PDP sponsor (as defined in section 1860D–41(a)(13)).
“(ii) EXCLUSION.—Such term does not include a beneficiary.

While this short law seems straightforward at first glance, there are a number of important definitions that are omitted, including: “not entitled,” “identified,” and “after reconciliation”—although the law includes a definition (for “knowingly”) that is not used in PPACA Section 6402(d). Thus, the law leaves open the critical question of when the 60-day period commences. In the absence of official guidance in the form of regulation or manual provisions from the Centers for Medicare and Medicaid Services (CMS), each organization must interpret and apply the rule within their existing compliance structure. This is where the rubber meets the road.

While neither CMS nor the Department of Health and Human Services Office of Inspector General (OIG) has spoken authoritatively about their interpretations of PPACA Section 6402(d), the New York State Office of the Medicaid Inspector General (NYS OMIG or OMIG) has taken the lead in attempting to interpret and apply the law in the context of the New York Medicaid program. Consequently, we note herein the interpretations of the NYS OMIG as providing one possible reading of a given provision.

What is “not entitled”? As noted above, the statute states “overpayments” are “funds that a person receives or retains under [Medicare or Medicaid] to which the person, after applicable reconciliation, is not entitled under such title.” There is no further definition of “not entitled,” and a reasonable question is whether the definition sought to change the common understanding of an overpayment. The Medicare Financial Management Manual defines overpayments as follows: “[o]verpayments are Medicare payments a provider or beneficiary has received in excess of amounts due and payable under the statute and regulations.” There are many case law decisions and other regulations that provide additional gloss on the definition of an “overpayment.” It appears likely that Congress did not mean to introduce a new analysis into what payments are overpayments under the current jurisprudence. If material conditions of payment are not met, it is likely courts will interpret overpayments to have been made. The NYS OMIG appears to agree that PPACA Section 6402(d) does not introduce a different standard of what constitutes an “overpayment,” though the OMIG may view other deficiencies (such as “lack of documentation”) as also constituting an overpayment. Disagreements over this issue are common between the enforcement and defense bars, but do not seem to be changed by the language of PPACA Section 6402(d) (4)(B). They may now be, however, of heightened importance.

What is “after applicable reconciliation”? Another term that appears in PPACA Section 6402(d) is “after applicable reconciliation.” Under the statute, “overpayment” means “any funds that a person receives or retains . . . after applicable reconciliation . . . .” Either the overpayment does not exist until the reconciliation is complete or, at least, the overpayment is reduced by the reconciliation process. But, clearly, these principles can have significant ramifications on when the 60-day clock starts running and what amount of overpayment needs to be refunded.

The Senate Committee Report referenced above included the concept of “reconciliation” in the context of cost reporting. It is not clear that Congress in PPACA intended “after applicable reconciliation” to be limited to the cost reporting arena. NYS OMIG has interpreted the term to apply to interim payments prior to cost report-based payment determinations, reconciliations related to Medicaid best price
determinations for prescription drugs, and Medicare credit balances (under CMS Form 838s – quarterly report of Medicare credit balances).

In what other ways might overpayments be subject to reconciliations? Other possibilities include calculation and reductions for copayments/deductibles and offsetting underpayments. The final amount due to Medicare or Medicaid would inevitably be reduced by such amounts and this process requires reconciliation. Indeed, in the context of the overall statute that requires not only a “report” but also a “refund” of an overpayment, providers and plans are well justified in seeing an obligation to perform the mathematical calculations necessary to arrive at the financial impact of the overpayment. Otherwise, they would not be in a position to issue the refund required by the statute. This is a reasonable reading of “after applicable reconciliation,” though it is not the only reading.

**When does the “cost report” deadline apply?**

PPACA Section 6402(d)(2) starts a clock for the refund and reporting of an overpayment expiring on the date that is 60 days after the date on which the overpayment was identified or “the date any corresponding cost report is due, if applicable.” As noted above, there is no explanation of when the cost report deadline applies. It could apply to only interim payments that must be resolved through the cost report. But it could be read to apply to all cost-reporting providers. Such providers have always had the opportunity to use the “attachment package” to the Medicare (and likely Medicaid) cost reports in order to process and adjust for overpayments received during the year or other discrepancies.

There is no settled answer to this question, although providers seeking to adjust reimbursement issues that must be settled through the cost report, such as disproportionate share hospital, graduate medical education and indirect medical education, Medicare bad debts, organ acquisition costs, or outliers, may need to rely on the cost-report deadline, and may be unable to comply with an earlier date. Good practice suggests working with fiscal intermediaries/administrative contractors to confirm the payors expect this process, and confirming correspondence including the report clearly is a best practice if an actual refund cannot be completed until the cost report is processed. It also seems reasonable that this later deadline would not be advisable for overpayments resulting from potential fraud, false claims, or knowing violations. Consequently, absent guidance from the agencies, complying with the cost reporting deadline is an important defense to remember, but it likely should not be employed as a regular practice.

**What does it mean to “identify” an overpayment? (When does the clock start?)**

In practice, the most challenging issue for plans and providers as a result of the changes in PPACA Section 6402(d) is knowing when the 60-day clock has started running. This requires knowing at what moment the organization can be said to have “identified” an overpayment. The term “identified” is not defined in the statute and, as noted above, there are no regulations interpreting this provision.

Possible interpretations about when an overpayment is deemed to have been identified vary widely. These possibilities include, among others:

1. When the organization has received any “whiff” of an overpayment, without any knowledge of whether the allegation is accurate or how much of an overpayment must be refunded;
2. When an organization has credible allegations that an overpayment has been received, and the amount of the overpayment has been determined using commercially reasonable methods and a responsible process; or
3. When the organization has absolute knowledge that an overpayment has been received, with no possible defenses or counterarguments and an absolute certainty of the amount of the overpayment to the penny.

There are, of course, other permutations of these standards, and likely standards in between the four outlined above. However, what this list does demonstrate is a continuum, with reasonable disagreements about when along the continuum an overpayment is “identified.” And the implications are material.

The NYS OMIG has proposed a standard of “identified” that falls at the early end of the continuum. OMIG stated identification means “the fact of an overpayment, not the amount of the overpayment has been identified. (e.g., patient was dead at time service was allegedly rendered, APG claim includes service not rendered, chargemaster had code crosswalk error).” Thus, in New York, the OMIG does not deem the ability to know the amount of the overpayment as a condition for having identified the overpayment.

OMIG draws comparison with language in PPACA Section 6402(d) from a proposed rule to amend 42 C.F.R. § 401.310 on overpayments that was introduced and withdrawn by CMS. CMS proposed that “[i]f a provider, supplier, or individual identifies a Medicare payment received in excess of amounts payable under the Medicare statute and regulations, the provider, supplier, or individual must, within 60 days of identifying or learning of the excess payment, return the overpayment to the appropriate intermediary or carrier.” OMIG notes the formulation of PPACA Section 6402(d)(2)(A) is similar to the language of the proposed rule.

It is possible, however, that the opposite conclusion could be drawn from the comparison. In the CMS proposed rule, the agency set forth the 60-day clock would not be triggered until the organization had either identified or “learned of” the overpayment. One could read “learning of” as a lesser standard of knowledge than “identifying,” thus starting the clock earlier. If that is the case, then Congress not employing the “or learning of” standard could have meant the 60-day clock would not start until the higher degree of knowledge is met. This formulation (“identifying or learning of”) also is the language found in many or most OIG corporate integrity agreements (CIAs).
It may be true that the New York approach is an easy standard for the government to apply (and it should result in funds flowing back to the payors earlier), such a standard may require a refund before the organization has had sufficient time to investigate the facts and before the organization is even able to calculate the amount of the overpayment. This leads to more questions, such as whether organizations would be required to submit interim or escrowed payment or make a refund well in excess of any possible overpayment. It is foreseeable that if this standard were to be applied, incorrect and premature refunds would routinely be made to payors merely to stop the running of the clock.

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The real problem as the rubber meets the road is that in many significant healthcare reimbursement questions (where it is now almost cliché to note the ambiguities, complexities, and morass of authorities) it simply is impossible to complete a responsible, thorough, and best-practices investigation within 60 days of the first allegation. Complex investigations routinely require the organization to (1) engage counsel and consultants, (2) interview witnesses, (3) secure and collect relevant documents (including voluminous electronic records and emails), (4) have the documents reviewed and analyzed, (5) conduct statistical analyses for necessary extrapolations, (6) address coinsurance and deductibles, (7) address secondary payors, and (8) take the other steps necessary before concluding that an overpayment has been made.

What other standards could an organization employ to determine whether an overpayment has been identified?

Absent regulation, plans and providers will need to adopt a standard for their own organization as to when an overpayment has been identified. Any of the above-referenced four standards on the continuum would be defensible. Selecting the most aggressive standard and timetable not only may require the organization to “do the impossible,” it also may conflict with other duties, such as the duties to charitable organization and trusts or to shareholders not to waste corporate assets.

The OIG has in its CIAs further employed several principles that recommend in favor of organizations establishing policies providing the opportunity to evaluate and investigate allegations before concluding an overpayment exists. A common formulation for OIG CIAs regards “reportable events,” and requires that “[i]f [Entity] determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, [Entity] shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists.” (Emphasis added). This formulation permits a reasonable opportunity to investigate allegations and also requires the organization to have made an affirmative determination that the allegations are correct. The 30 days do not start running while these steps are underway. Rather, the clock starts after the steps are complete. Organizations under CIAs likely will interpret their CIA terms as consistent with Section 6402(d). If they are justified in doing so, why would other organizations not under CIAs have a more stringent set of duties?

If the duty is not merely to disclose a problem, but also to be in a position to make a “refund” “after reconciliation,” then an entity would be justified in implementing a policy (similar to the OIG’s CIA approach) that it will not have identified an overpayment until after a proper investigation of the allegations and knowledge of the amount needed to be refunded. Of course, such a policy would also require the entity to promptly and timely conduct the investigation and review.

What should an organization’s overpayment policy say?

There likely are different interpretations of Section 6402(d) depending on the context. First, in a defense to an FCA case where the relator or plaintiff argues an organization knew of overpayments but failed to refund them, the organization may not have developed sufficient “organizational knowledge” to have actually “identified” an overpayment. Second, on an ad hoc case-by-case basis, an organization may elect to be far more transparent with the payors early on, even if not required by the statute. This may militate in favor of making a disclosure of possible overpayments before the entity has the ability to calculate the amount to be refunded. While this may not be required by the statute, it may be a good protective practice. And, finally, there may be a different approach for an across-the-board policy applicable to the general running of the organization’s finance and compliance operations. In all likelihood it is in this third context that the principles will be most often implemented.

The organization needs to be thoughtful not to waive the right to argue in defense that the statute’s correct application may be more protective than the policy the organization voluntarily adopts. Additionally, the policy should not prohibit an earlier or interim report if the context and circumstances merit such a disclosure prior to a refund.

Absent regulations, what policy should an organization adopt? Plans and providers are experimenting with different
policies consistent with their organizational cultures, experiences, and internal expertise. We have surveyed and worked with a number of healthcare providers that have sought to memorialize their approach to PPACA Section 6402(d) in policies. Organizations are attempting to balance competing duties, apply the law fairly, and mitigate risk. Our survey revealed many different and good-faith approaches in the market. These range from determining that an overpayment has been identified:

- Even if the final amount of the overpayment has not yet been quantified or otherwise determined;
- Following a mandatory review and determination by a specific team of professionals that the overpayment exists;
- After research of relevant authorities, determination of the amount of the overpayment, as well as start and stop dates and confirmation by the compliance officer;
- Upon the date of the final report by internal audit (much like the rules applicable to state Medicaid plans returning overpayments to the federal government); or
- Upon approval by the compliance officer or chief financial officer.

**A proposed overpayments policy**

In the absence of regulation or case law interpreting the parameters of PPACA Section 6402(d), organizations are establishing policies they believe meet the requirements of the law and work within their existing systems. The approaches mentioned above all likely work for the entities that created them.

For organizations that have not yet adopted a policy, the following is a proposed approach that seeks to balance many of the considerations discussed above. An organization could establish a policy that: an overpayment is “identified” when an entity has “credible evidence” that it is “probable” that it has received a “quantifiable” overpayment. What do these terms mean?

First, the entity would require “credible evidence.” This is intended to be a higher degree of knowledge than the “credible allegation” standard recommended by NYS OMIG, but less than certainty. “Credible evidence” is information that, considering its source and the circumstances, supports a reasonable belief there has been an overpayment. This includes an opportunity to take time for at least a preliminary examination of the evidence to determine its credibility.

Second, the credible evidence must support that it is “probable” an overpayment has been received. “Probable” is not the same as “probably.” It is derived from the financial accounting standards (FAS) used in generally accepted accounting principles (GAAP). These are the principles that inform an organization whether a loss contingency should be accrued because “the future event or events are likely to occur.” “Probable” can be contrasted with other important terms used in FAS 450. Probable is a higher degree of confidence than “reasonably possible” (“the chance of the future event or events occurring is more than remote but less than likely”) and “remote” (“the chance of the future event or events occurring is slight”). But it is a lesser degree of confidence than a “virtual certainty.” To determine that the overpayment is probable, the organization is entitled to conduct an appropriate review or investigation. This requires:

- A systematic inquiry into the facts and timing of the alleged overpayment;
- Reasonable consultation with counsel;
- Review of potential legal defenses; and
- A reasonable period of time to review the facts, law, and circumstances of a claim or claims giving rise to an overpayment.

The NYS OMIG has recommended that organizations create a record to demonstrate to the government that the organization collected or attempted to address allegations of overpayments. This is solid advice regardless of the underlying policy against which the overpayment identification processes are tested. The OMIG’s recommendation included:

- Developing standard form to document employee’s internal disclosure
- Documenting interviews
- Documenting evidence and means to determine if credible
- Recording employees involved in deliberations and decisions
- Determining what to report and what to return

Third, the overpayment must be “quantifiable.” Organizations have flexibility in applying the “quantifiable” standard. Options range from:

- Completing the collection of financial and reimbursement data necessary to calculate the overpayment, even though the final summation has not been concluded; to
- Could be known following exhaustive effort, research, statisticians’ review, etc.

The first option, also known as the “push the button” approach, requires that the overpayment is knowable if the organization can simply push a button in the software to determine the overpayment. This standard is designed to avoid the criticism that an organization might intentionally avoid finalizing its quantification to avoid having to commence the repayment process. If the
ability to conclude the quantification is there, the information has been assembled, and with minimal effort the refund could be calculated, then the overpayment is “quantifiable” even if it is not “quantified.” The second option leaves the organization in the difficult position of having an overpayment that must be refunded, but that cannot be readily quantified. There may be other options between these two, though to make a policy workable an organization must adopt standards that can be known, taught, and audited.

The above-described proposed policy is only one possible option for providers. It should be noted that this proposal is for consideration and discussion purposes only. It has not been approved by CMS or any other agency. However, it provides a framework against which an organization can choose to calibrate their internal policies. Regardless of what policy is chosen, the following suggestions should be considered:

❯❯ Do not create unworkable policy bureaucracy;
❯❯ Do allow flexibility for changing information during an investigation;
❯❯ Do demonstrate effectiveness of the compliance plan;
❯❯ Do not establish a policy that conflicts with internal accounting policies without input from auditors and legal counsel (e.g., public companies and private companies that follow GAAP need to comply with GAAP obligations on reserving for probable contingent liabilities); and
❯❯ Do implement robust training and education around the policy, how to spot overpayments, requirements for internal (or external) reporting, and the organization’s commitment against retaliation. 

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Endnotes
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2. See, e.g., 42 U.S.C. §§ 1395ccc(a)(1)(C), 1395g(a), and 1320a-7b(a)(3).
5. Id.
8. Id. at n. 15.
9. Medicare Financial Management Manual (100-06) Ch. 3, § 90. See Social Security Act (SSA) § 1877(b) and (c), 42 U.S.C. § 1395gg(a) and (c), Section 1879 of the SSA, 42 U.S.C. § 1395pp, provides that when Medicare coverage and payment is excluded pursuant to Section 1862 of the Act, 42 U.S.C. § 1395y, payment may nevertheless be made for items of services if neither the supplier nor the beneficiary knew, and could not reasonably be expected to have known, that the items or services would not be covered or payable by Medicare. See also 42 C.F.R. § 411.426.
11. See SSA § 1128J(d); 42 U.S.C. § 1320a-7k(d).
12. See SSA § 1128A(a); 42 U.S.C. § 1320a–7a(a).
13. See SSA § 1128A; 42 U.S.C. § 1320a-7a and SSA § 1902(a); 42 U.S.C. § 1396a(a).
14. The NYS OMIG interpretations have been taken from various public statements of the Office posted on the OMIG website www.omig.state.ny.us/data/index.php?option=com_content&task=view&id=204&Itemid=30 (downloaded on Apr. 19, 2011). Some of these principles may be incorporated into regulations and others may remain sub-regulatory guidance. This article does not distinguish between the two and the reader is urged to consult the primary sources as to the actual legal requirements for New York Medicaid contracted entities.

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