Published on *The National Law Review* https://natlawreview.com

Overpayment Rule and Implied False Claims Theory: "What You Don't Know Can Still Hurt You"

Article By:

Steven J. Chananie

Michael G. McKinnon

Linda Igarashi

Erica J. Kraus

In 2010, the ***Affordable Care Act ("ACA")*** enacted new rules governing overpayments made by the *Medicare* and *Medicaid* programs. Under these rules, providers have 60 days from the date that the overpayment has been identified to return the overpayment or face penalties and treble damages under the ***False Claims Act ("FCA")***. As described below, recent regulations have clarified some of the issues surrounding the ACA obligation to refund overpayments, at least for overpayments under Medicare Parts A and B. But, determining whether a provider has "identified" an overpayment – and thus started the 60 day countdown – can still be nuanced and complex. Diligent providers that have proactive and robust compliance and audit functions in place may find some comfort, since such providers are presumably able to respond quickly to credible information that there has been a potential overpayment, as required by the new regulations, and thereby have a reasonable period of time to conduct an investigation and quantify the amount of any overpayment before the 60 day clock begins to run.

The new Part A and B regulations, however, do not address an important issue that remains unclear under the law: what types of non-compliance result in overpayments. Jurisprudence developed in the context of the FCA may be an important source of law for understanding this issue; if non-compliance with a particular requirement predicates liability under the FCA by rendering claims materially false, it is likely that payments received based on such claims would be overpayments that the claimant is obligated to report and return. Therefore, law defining the types of non-compliance that can predicate FCA liability may also speak to the types of non-compliance that can lead to an overpayment under the ACA.

Courts have agreed that, under the FCA, claims can be false either because they contain factually false information on their face, or because a claimant falsely certifies to compliance with a statutory, regulatory, or contractual provision ("false certification"). Until recently, however, the federal circuit courts were split as to whether such a false certification must be "express" – an explicit promise to

comply with certain provisions – or whether it may also be "implied" simply through the act of submitting a claim. Those courts that accepted this latter "implied certification" theory of FCA liability were further split into two camps. While some took a narrow approach that only a failure to adhere to a requirement that is expressly characterized as a "condition of payment" constitutes a false claim, others had held that a false claim can emanate from the failure to comply with a "condition of participation" in the applicable government program. Under this latter view, in submitting a claim to Medicare or Medicaid, the provider impliedly certified that it had complied with *all* regulatory requirements governing the delivery of that service, not only requirements that expressly stated that they were conditions of payment. On this theory, failure to comply with potentially any regulatory requirement relating to the service provided and being billed for, could have lead to false claim liability under the FCA and exposed the provider to civil penalties, treble damages and *qui tam* liability.

The U.S. Supreme Court recently resolved these disputes about the viability and scope of the implied certification theory in its decision in *Universal Health Services, Inc. v. United States and Commonwealth of Massachusetts ex rel., Julio Escobar and Carmen Correa*. The Court upheld the First Circuit's determination that implied certification is a viable theory of FCA liability, but adopted a novel analytical framework for determining what types of non-compliance can predicate liability. Rather than side with either of the two camps described above, the Court held that FCA liability *can* be predicated on non-compliance with requirements that are not expressly characterized as conditions of payment, but nonetheless that *not all* non-compliance can predicate FCA liability. Rather, the Court held that non-compliance can predicate FCA liability if the non-compliance renders the information contained in a claim for payment a "half-truth", and the misrepresentation arising from the non-compliance is material to the government's decision to pay the claim.

Given the already daunting complexity and risk healthcare providers currently face in navigating the multitude of Medicare and Medicaid coding, billing and other regulations, the implied certification theory has been a cause of great concern for providers receiving Medicare and Medicaid reimbursement. In upholding the implied certification theory, the Supreme Court has offered little solace to providers concerned about the threat of *qui tam* actions under the FCA. Although the Supreme Court's emphasis on the rigor of the materiality requirement, as well as its newly formulated "half-truth" requirement, may give some comfort that not every instance of non-compliance will lead to FCA liability, it is still unclear how these elements will be interpreted and applied by the lower courts.

Without the precedential framework that allowed providers and suppliers to distinguish with some reliability between conditions of payment and conditions of participation – and, therefore, at least in circuits that relied on that distinction, to identify the types of non-compliance that created the most FCA risk – it will be difficult to determine when non-compliance with any of the myriad complex regulations governing health care providers and suppliers is likely to predicate FCA liability. Potential FCA exposure under *United Health Services*, therefore, is currently extremely uncertain. To the extent that the concept of implied certification informs the proper understanding of the types of non-compliance that can lead to overpayments under the ACA, this ambiguity also further muddies the water as to the circumstances under which non-compliance may create an obligation for providers and suppliers to report and return funds to Medicare or Medicaid.

I. The Affordable Care Act's 60-Day Rule

The ACA includes a statutory requirement that a person who receives an "overpayment" from Medicare or Medicaid must "report and return" the overpayment within 60 days of the date on which

the overpayment was "identified" (or the date any corresponding cost report is due) (the "**60-Day Rule**").[1] An "overpayment" is any funds received or retained which, "after reconciliation," the person is not entitled. An "overpayment" applies to funds received or retained under Titles XVIII and XIX, which include not only fee-for-service Medicare (Parts A and B) and Medicaid, but also Medicare Advantage (Part C) and Medicare Part D. The overpayment must be reported and returned "as appropriate" to the Secretary, the State, an intermediary, a carrier or a contractor, with notification "in writing of the reason for the overpayment."[2]

Compliance with the 60-Day Rule is critically important to providers and suppliers because an "overpayment" retained after the deadline becomes an "obligation" under the FCA. An "obligation," under the FCA means an "established duty, whether or not fixed," arising from among other things, the "retention of any overpayment."[3] Knowingly concealing and improperly avoiding or decreasing an obligation to pay the government creates liability under the FCA.[4] Knowingly includes not just having actual knowledge, but also acting with "reckless disregard" or "deliberate ignorance."

A. When Is an Overpayment "Identified"?

On February 12, 2016, interpretive regulations for Medicare Parts A and B overpayments were finalized by the Center for Medicare and Medicaid Services (**"CMS"**) and clarified a number of key issues for Part A and B providers (the "**Part A and B Final Rule**").[5] Regulations promulgated previously for Medicare Parts C and D overpayments clarified key issues for Medicare Advantage organizations and Part D sponsors who receive overpayments, but did not address the obligations of providers.[6] There are no regulations for Medicaid overpayments, although CMS has stated in commentary that such regulations may be forthcoming in the future.[7] Prior to the Part A and B Final Rule from CMS, a major question remained regarding the standard for identification and whether an overpayment can be identified before it is quantified. In the Part A and B Final Rule, CMS defines identification of an overpayment to start the 60 day clock as 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."[8] CMS has clarified "that part of the identification is quantifying the amount, which requires a reasonably diligent investigation."

In short, CMS is allowing for an opportunity to quantify the overpayment before the 60-day clock starts. This standard, however, does not necessarily apply to claims under Medicaid or Medicare Parts C and D. The District Court in *United States ex rel. Kane et al. v. Healthfirst, Inc., et al.,* 120 F. Supp.3d 370 (August 3, 2015), held that the ACA and the FCA do apply to overpayments from Medicaid and found that the 60-day ACA clock starts after the provider receives notice of the potential overpayment, not when the overpayment is quantified.[9] The court adopted the government's position that identification includes situations where "a person is put on notice that a certain claim may have been overpaid." Based on the court's interpretation of the meaning of "identification," the 60-day ACA clock may begin, and possibly for Medicaid overpayments, expire before a provider has had sufficient time to complete a reasonable investigation. The decision in the case, however, was issued well before the Part A and B Final Rule was issued, and it is uncertain whether the District Court in *Healthfirst* would have analyzed the issues under Medicaid in light of the clear guidelines in the Part A and B Final Rule.

Regardless, the *Healthfirst* decision is instructive as to the dangers of delay in conducting an internal investigation and quantifying the overpayment; and it underscores the importance of proceeding with "reasonable diligence" and "with all deliberate speed." In any case, and especially with Medicaid overpayments, if the investigation and quantification process is going to take more than 60 days, consider providing an interim report to the government.

It is uncertain if or when CMS might issue regulations concerning Medicaid overpayments. In the meantime, it might be reasonable to assume that such regulations will mirror the Part A and B regulations (as both situations invoke overpayments to providers), rather than Part C and D regulations (which address overpayments to Medicare Advantage organizations and Part D sponsors). But there are no assurances that this is what CMS would do, and in the meantime, *Healthfirst* is still valid case law in New York, at least.

B. When Does the Clock Start for Part A or B Overpayments?

CMS stated that "[t]he 60-day time period begins when either [(A)] the reasonable diligence is completed or [(B)] on the day the person received credible information of a potential overpayment if the person failed to conduct reasonable diligence and the person in fact received an overpayment."[10] To determine whether a person conducted reasonable diligence, CMS lays out a two-part test. CMS indicates that 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."

- Test 1 – Proactive Compliance

CMS stressed that "proactive compliance activities are necessary to monitor for receipt of overpayments." As a result, providers and suppliers "have a clear duty to undertake proactive activities to determine if they have received an overpayment or risk potential liability for retaining such overpayment." If there are "no or minimal compliance activities," the provider will face potential liability under the "identified" standard, because the provider will not have been acting with reasonable diligence, even if the provider has not received credible information of an overpayment.

The importance of having a robust and effective compliance program has for many years been widely accepted as a necessity. The CMS commentary to the Part A and B Final Rule, however, now makes explicit that a robust compliance program is a "clear duty" that is necessary to address and minimize FCA liability for overpayments. Indeed, the failure to have an appropriate compliance program, with robust procedures, could result not only in the 60 day clock running immediately upon the receipt of credible information of an overpayment, but also to FCA liability for an initially *unidentified* overpayment that is only discovered at a much later date.

- Test 2 – Respond to Credible Information

Once a provider has obtained "credible information" of a potential overpayment, the provider must act with "reasonable diligence" and conduct an "investigation . . . in good faith and in a timely manner by qualified individuals." Examples of credible information provided by CMS include:

- **Hotline Call / Complaint**. Whether a hotline call qualifies as "credible information" that triggers the need to investigate turns on the specific facts and circumstances: e.g., how detailed is the call; and is there a pattern of calls on the same subject. Thus, a provider does not necessarily have to investigate every call, but care must be taken not to dismiss seemingly baseless calls/complaints that could later be deemed to have been credible.

- **Significant, Unexplained Increase in Medicare Revenues**.

- **Physician Practice**. Are there unusually high profits "in relation to hours worked or RUVs associated with the work?"

- **Government Audit**. Findings from a government audit require a response, which can involve a root cause analysis and an investigation that goes beyond the scope of the government audit. (Although if the provider is appealing, it may be "pre-mature" according to CMS to "institute a reasonably diligent investigation").

- **Cost Report**. If the Medicare Administrative Contractor ("**MAC**") notifies a provider of an improper cost report payment, this will likely be credible information requiring a review of prior cost reports.

C. Definition of Overpayment

CMS defines overpayment in the same way as defined in the ACA, which is "any funds that a person receives or retains [under Medicare or Medicaid programs] to which the person, after applicable reconciliation, is not entitled."[11]

In the Part A and B Final Rule, CMS provides the following examples of common types of overpayments:

- Payments for non-covered services;

- Payments in excess of the allowable amount for an identified covered service (e.g., due to upcoding or miscoding);

- Errors and non-reimbursable expenditures in cost reports;

- Duplicate payments;

- Payment received when another payor had the primary responsibility for payment; and

- Billing for services that have inadequate documentation (CMS: "sufficient documentation is a longstanding prerequisite to Medicare coverage").

In the commentary to the Part A and B Final Rule, CMS explains that it is "unable to make blanket statements or address every factual permutation in this rulemaking, and thus it is not feasible for [the agency] to enumerate all specific examples of overpayments." CMS instructs providers and suppliers to "analyze the facts and circumstances relevant to their situation to determine whether an overpayment exists."

In circumstances where a the provider discovers a compliance issue unrelated to billing, coding or reimbursement, further legal analysis will be necessary to determine whether the non-compliance itself is of the nature that it should be deemed to have resulted in an overpayment. In its recent decision in the *Universal Health Services* case, discussed further below, the U.S. Supreme Court explained the circumstances under which non-compliance makes a claim false under the FCA. The Court's analysis differs substantially from the tests previously applied by most courts and has not yet been applied to determining when an overpayment exists under the ACA; therefore, substantial

uncertainty remains as to what types of non-compliance will result in overpayments that must be reported and returned.

D. Process for Reporting and Returning Overpayments

Under the Part A and B Final Rule, to report and return Medicare Parts A and B overpayments, providers are instructed to use existing processes. Specifically, the Part A and B Final Rule states that providers and suppliers must use an applicable claims adjustment, credit balance, self-reported refund process, or other appropriate process to report and return Medicare Parts A and B overpayments. CMS thereby provided much needed flexibility in how overpayments can be reported and refunded. This includes, for instance, using the routine claims adjustment process with the local MAC, presumably rather than doing a full voluntary disclosure to the MAC's voluntary refund unit. The appropriateness of using the routine adjustment process has long been a point of uncertainty, which now seems to be resolved by CMS. Similarly, hospitals may also continue to use the established quarterly Medicare process for reporting credit balances – even if using such a process might take the provider beyond 60 days of identifying the credit balance.

Regardless of the process used, the refund should include an explanation of the statistical sampling methodology used if an overpayment was calculated by extrapolation.

II. Import of the Universal Health Services Case

In the recently decided *Universal Health Services* case, the U.S. Supreme Court held that the implied certification theory is valid, but declined to limit the theory to non-compliance with expressly designated conditions of payment *or* to extend it to non-compliance with any requirement. Rather, the Court looked to the common law definition of fraud and the FCA's materiality requirement to limit implied certification theory to instances in which: (1) a defendant submits a claim that does not merely request payment, but also makes specific representations about the goods or services provided, (2) knowingly fails to disclose the defendant's non-compliance with statutory, regulatory, or contractual requirements, (3) this omission renders these representations misleading, and (4) the resulting misrepresentation is material to the Government's decision to pay the claim.

It is not yet clear what types of non-compliance will meet this test. In *Universal Health Services*, defendant had allegedly failed to meet Medicaid requirements for the qualifications of its professional staff. According to the Court, by submitting claims for payment with payment codes corresponding to specific counseling services and National Provider Identification numbers corresponding to specific job titles, Defendant had represented to Massachusetts Medicaid that it had provided these services through professionals with certain qualifications. Because "[a]nyone" given this information would conclude, incorrectly, that Defendant had "complied with core Massachusetts Medicaid requirements", and Defendant had not done so, its claims constituted misrepresentations; the provision of services by improperly supervised or licensed individuals undermined the very integrity of the services provided, and thereby undermined the provider's ability to bill Medicare or Medicaid for those services.

However, the Court does not specify what other types of non-compliance might also make representations in claims into "misleading half-truths." Health care providers and suppliers are subject to a plethora of complex regulations, ranging from those that are centrally related to adequately providing the care for which they claim payment (for instance, the staff qualification regulations at issue in *Universal Health Services*) to those that are much more tangentially related to patient care. For instance, home health agencies are required by federal regulation to have

personnel practices supported by appropriate, written personnel policies. While a home health agency could be subject to sanction by CMS for failure to comply with this regulation, it is not clear that a reasonable person considering a claim by the agency for payment for the home health services it provided would conclude anything about the agency's compliance or non-compliance with this regulation; as such, it is not clear that non-compliance with this regulation would render the representations on the agency's claim forms misleading half-truths.

Similarly, while the Court emphasized the rigor of the requirement that, to predicate FCA liability, non-compliance be material to the Government's decision to pay a claim, it is not clear how or if the lower courts will carry out the Court's instruction that plaintiffs be required to "plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality." While, particularly in the health care context, the government and its contractors may often pay claims despite their awareness of the claimant's technical or marginal non-compliance with legal requirements – a factor that the Court stated would be relevant to materiality – it is not clear exactly how courts may weigh various potentially relevant factors to make this determination, or how they will be able to make such a determination at the motion to dismiss stage.

As discussed, because the implied certification theory of FCA liability explains what types of non-compliance can make a claim false for FCA purposes, it may also be relevant to understanding the types of non-compliance that may create overpayments under the ACA. The Supreme Court has now affirmed the viability of this theory and offered a new analysis of the circumstances in which it applies. This analysis is likely to have implications for overpayment liability under the ACA as well; where non-compliance creates half-truths that are material to the government's decision to pay a claim, such non-compliance may not only predicate FCA liability, but also create overpayments that must be reported and returned. In any event, the Supreme Court's affirmation of implied certification theory in the *Universal Health Services* case, coupled with the new ACA regulations on overpayments, are a warning to providers to build and maintain comprehensive, robust and active compliance programs, including regular audits to detect and correct not only billing and coding errors but also deficiencies in all other regulatory areas.

[1] 42 U.S.C. §1320a–7K(d).

[2] 42 U.S.C. §1320a–7K(d).

[3] 31 U.S.C. §3729(b)(3) (added by FERA in 2009).

[4] 31 U.S.C. §3729(a)(9)(G).

[5] 42 U.S.C. §§401.301–401.305 (Effective March 14, 2016).

[6] 42 CFR §§422.326, 423.360.

[7] In 42 U.S.C. §§401.301–401.305, CMS emphasizes that overpayments from Medicaid are still subject to the 60-Day Rule, even in the absence of implementing regulations.

[8] 42 U.S.C. §§401.301–401.305.

[9] The U.S. District Court for the Southern District of New York on August 3, 2015 denied defendants' motion to dismiss. Relator Kane filed a qui tam action under the federal and NYS FCAs. The government intervened against the defendant health system Continuum Health Partners and two of its hospitals. The case involves overpayments to Medicaid and allegations of non-compliance with the ACA's 60-Day Rule.

[10] 42 U.S.C. §§401.301–401.305.

[11] 42 U.S.C. §1320a–7K(d)(4)(B).

National Law Review, Volume VI, Number 195