Reverse False Claims and 60-Day rule for Medicare and Medicaid

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Reverse False Claims Provision (1986 Act)

Prior to 2009, the False Claims Act provided that a person who

"knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government"

was liable to the United States for civil penalties and treble damages. 31 U.S.C. § 3729(a)(7) (2000).

Divergent Caselaw on "Obligation"

Some courts required the "obligation" to be fixed or sufficiently certain "to give rise to an action of debt at common law" and did not encompass "contingent obligations."

See United States ex rel. American Textile Manufacturers Institute, Inc. v. The Limited, Inc., 190 F.3d 729, 738 (6th Cir. 1999)

Divergent Caselaw on "Obligation"

Other courts construed "obligation" to encompass instances in which a party is required to pay money to the Government even if "the sum has not been precisely determined" and even if the payment requirement could be waived by the Government.

See United States ex rel. Bahrani v. Conagra, Inc., 465 F.3d 1189 (10th Cir. 2006)

FERA and Reverse False Claims

In 2009, Congress passed the Fraud Enforcement and Recovery Act, Pub. Law 111-21, 123 Stat. 1617 (2009) ("FERA"). FERA extensively amended the FCA, including the reverse false claims provision.

FERA False Claims Act Provision

The amended FCA provides that a person who

"knowingly makes, uses, or causes to be made or used, a false record or statement <u>material to</u> an obligation to pay or transmit money or property to the Government, <u>or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government"</u>

is liable to the U.S. for civil penalties and treble damages. 31 U.S.C. § 3729(a)(1)(G) (emphasis added to indicate new language included in the FERA amended provision).

FERA Defines of "Obligation"

FERA amended the FCA by including the following definition of "obligation" –

"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."

Pub. L. No. 111-21, § 4(a)(2), 123 Stat. at 1623 (codified at 31 U.S.C. § 3729(b)(3)) (emphasis added)).

FERA Senate Report No. 111-10

The Senate Report specifically noted with disapproval the two cases referenced above: The Limited and Q Int'l Courier. The Report disapproved The Limited's definition of "obligation" on the ground that it included only obligations that were established and fixed in all particulars. S. Rep. No. 111-10, at 14, fn.10 (2009), reprinted in 2009 U.S.C.C.A.N. 430, 441. See also id. at 14 (citing with disapproval United States v. Q Int'l Courier, Inc., 131 F.3d 770, 774 (8th Cir. 1997), which held that for there to be FCA liability, the obligation "must be for a fixed sum that is immediately due").

FERA Senate Report No. 111-10

The Senate Report expressly approved the *Bahrani* decision, 465 F.3d 1189, for its construction of "obligation," *i.e.*, the absence of a fixed monetary obligation does not preclude a reverse false claim action. *See* S. Rep. 111-10 at 14, fn. 14.

FERA Senate Report No. 111-10

A "reverse" false claim violation is committed "once an overpayment is knowingly and improperly retained, without notice to the Government about the overpayment," S. Rep. No. 111-10, at 15, and an "obligation" exists "whether or not the amount owed is yet fixed." *Id.* at 14.

2010 Affordable Care Act 60-day report and return provisions

Recipients of Medicare and Medicaid funds who have "received an overpayment" must "report and return the overpayments" to HHS or the State, as appropriate.

See 42 U.S.C. § 1320a-7k(d)(1).

2010 Affordable Care Act 60-day report and return provisions

ACA defines overpayment –

"any funds that a person receives or retains under [the Medicare or Medicaid programs] to which the person, after applicable reconciliation, is not entitled."

42 U.S.C. § 1320a-7k(d)(4)(B).

2010 Affordable Care Act 60-day report and return provisions

An "overpayment must be reported and returned" within "60 days after the date on which the overpayment was identified."

See 42 U.S.C. § 1320a-7k(d)(1)-(2).

Enforcement of 60-day report and return provisions

In a provision entitled "Enforcement," the ACA provides –

"[a]ny overpayment retained by a person after the deadline for reporting and returning the overpayment . . . is an obligation (as defined in section 3729(b)(3) of [the False Claims Act]) for purposes of section 3729 of such title."

42 U.S.C. § 1320a-7k(d)(3).

Short Version of Report and Return Requirements

A person who has "received an overpayment" must report and return such overpayment within "60 days after the date on which the overpayment was identified" and if the recipient knowingly fails to do so, that recipient has violated the False Claims Act.

42 U.S.C. § 1320a-7k(d).

CMS Final Rule for Part C and Part D

On May 23, 2014, CMS issued its final rule to implement the reporting and return of overpayments provisions of the ACA with respect to the Part C Medicare Advantage program and the Part D Prescription Drug program.

See U.S. Dep't of Health & Human Servs., Ctrs. for Medicare& Medicaid Servs., Medicare Program; Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 79 Fed. Reg. 29844 (May 23, 2014) (the "CMS Rule Announcement").

CMS Final Rule for Part C and Part D

In its final rule, CMS adopted the definition of "overpayment" in the ACA and generally required that Medicare Advantage ("MA") organizations and Part D plan sponsors to return "identified overpayments" within 60 days. *See* 42 C.F.R. §§ 422.326, 423.360

CMS Final Rule for Part C and Part D (Defines "Identified Overpayment")

CMS defined "[i]dentified overpayment" to mean that the MA organization or Part D sponsor "has identified an overpayment when the [entity] has determined, or should have determined through the exercise of reasonable diligence, that [it] has received an overpayment." *Id.* §§ 422.326(c), 423.360(c) (emphasis added).

CMS Final Rule for Part C and Part D (Reasonable Diligence – Proactive/Reactive)

Proactive Reasonable Diligence: CMS explained that "reasonable diligence" "at a minimum" included "proactive compliance activities conducted in good faith by qualified individuals to monitor for the receipt of overpayments." 79 Fed. Reg. at 29924 CMS noted that conducting proactive compliance activities "does not mean that the person has satisfied the reasonable diligence standard in all circumstances." *Id*.

CMS Final Rule for Part C and Part D (Reasonable Diligence – Proactive/Reactive)

Reactive Reasonable Diligence: CMS observed that "in certain circumstances, for example, reasonable diligence might require an investigation conducted in good faith and in a timely manner by qualified individuals in response to credible information of a potential overpayment." 79 Fed. Reg. at 29924

"Identify" Does Not Mean Actual Knowledge

CMS specifically rejected commenters' suggestions that "identify" be defined to require "actual knowledge" --

If the requirement to report and return overpayments applied only to situations where the MA organization or Part D sponsor has actual knowledge of the existence of an overpayment, then these entities could easily avoid returning improperly received payments and the purpose of the section would be defeated. Thus, we decline to read a narrow actual knowledge limitation into the law as suggested by commenters.

79 Fed. Reg. at 29924

CMS Final Rule Part C and D (Enforcement and Look-back Period)

CMS's final rule provides that "[a]ny overpayment retained by an [MA or PDP entity] is an obligation under [the FCA] if not reported and returned in accordance with paragraph (d) of this section." 42 C.F.R 422.326(e); 423.360(e).

Lookback Period: "An [MA or PDP entity] must report and return any overpayment identified for the 6 most recent completed payment years." 42 C.F.R 422.326(f); 423.360(f).

CMS Final Rule for Parts A and B

CMS issued the final rule for the 60-day report and return requirement for Parts A and B on February 12, 2016. 81 FR 7654

The final rule adopted the ACA definition of overpayment ("funds that a person has received or retained under [Medicare] to which the person, after applicable reconciliation, is not entitled under [Medicare]").

42 C.F.R. 303

The rule applies to providers and suppliers and requires such persons to report and return overpayments as set forth in the final rule.

42 C.F.R. 401.305

Overpayment is Broadly Defined

CMS specifically rejected the proposal of a number of commenters for "overpayment" to be defined to exclude overpayments not caused by the provider or supplier or that were otherwise outside of their control, e.g., if the MAC makes a duplicate payment, pays for a non-covered service due to a contractor edit problem, or fails to properly implement a national or local coverage decision.

Overpayment is Broadly Defined

CMS stated that "an overpayment must be reported and returned regardless of the reason it happened – be it a human or system error, fraudulent behavior or otherwise."

81 FR 7656

CMS also stated that an overpayment can exist because of insufficient documentation and lack of medical necessity.

81 FR 7658

Overpayment is Broadly Defined

CMS is clear that claims resulting from kickbacks or Stark violations are also overpayments and that full amount paid for such claims is the amount of the overpayment. 81 FR 7658, 7659.

However, CMS also acknowledged: "in many instances, a provider or supplier is not a party to, and is unaware of the existence of, an arrangement between third parties that causes the provider or supplier to submit claims that are the subject of a kickback. . . . For this reason, we stated that we believe that providers and suppliers who are not a party of a kickback arrangement are unlikely in most instances to have 'identified' the overpayment that has resulted from the kickback arrangement, therefore would have no duty to report or repay it."

Overpayment is Broadly Defined

Where a provider or supplier *has* identified kickback-tainted claims, such overpayments must be reported. However, CMS states:

"Although the government may always seek repayment of claims paid that do not satisfy a condition of payment, where a kickback arrangement exists, HHS's enforcement efforts would most likely focus on holding accountable the perpetrators of that arrangement. Accordingly, we would refer the reported overpayment to OIG for appropriate action and would suspend the repayment obligation until the government has resolved the kickback matter. ...

Thus, if the provider has not identified the kickback or if it reported it when it did identify the kickback, 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 or supplier, except in the most extraordinary circumstances."

81 FR 7659.

CMS Final Rule for Parts A and B (Identification of Overpayment)

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."

"A person should have determined that the person received and overpayment and quantified the amount of overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment."

42 C.F.R. 401.305(2)

Parts A and B (Reasonable Diligence)

"The regulation uses a single term – reasonable diligence – to cover both proactive compliance activities to monitor claims and reactive investigative activities undertaken in response to receiving credible information about a potential overpayment. We believe that compliance with the statutory obligation to report and return received overpayments requires both proactive and reactive activities."

81 FR 7661

CMS further stated that "we believe that undertaking no or minimal compliance activities to monitor the accuracy and appropriateness of a provider or supplier's Medicare claims would expose a provider or supplier to liability under the identified standard articulate in this rule based on the failure to exercise reasonable diligence if the provider or supplier received and overpayment." *Id.*

Parts A and B (60-day deadline)

- (1) A person who has received an overpayment must 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 payment was identified.
- (ii) (ii) The date any corresponding cost report is due, if applicable.
- 42 C.F.R. 410.305(b)(1).

Parts A and B (Reasonable Diligence and 60-Day Clock)

Comments to Final Rule showed concern about insufficient time to conduct an investigation into overpayments and still comply with the 60-day report and return rule.

In response, CMS adopted the "reasonable diligence" standard and included it in the text of the final rule.

81 FR 7662.

Parts A and B (Reasonable Diligence and 60-Day Clock)

"[R]easonable diligence" is "demonstrated through the timely, good faith investigation of credible information, which is at most 6 months from receipt of the credible information, except in extraordinary circumstances." 81 FR 7662.

CMS chose 6 months as a benchmark for timely investigation "because we believe that providers and suppliers should prioritize these investigations and also recognize that completing these investigations may require the devotion of resources and time." *Id.*

Parts A and B (Reasonable Diligence and 60-Day Clock)

"A total of 8 months (6 months for timely investigation and 2 months for reporting and returning) is a reasonable amount of time, absent extraordinary circumstances. . . . [which] may include unusually complex investigations that the provider or supplier reasonably anticipate will require more than six months to investigate, such as [Stark violations] . . ., natural disasters or state of emergency."

81 FR 7662.

Or

Parts A and B (How to Report)

To satisfy the reporting obligation, a person "must use an applicable claims adjustment, credit balance, self-reported refund or other reporting process set for the by the applicable Medicare contractor [i.e., the MAC] to report an overpayment"

Make "disclosure under the OIG Self-Disclosure Protocol or the CMS Voluntary Self-Referral Protocol resulting in a settlement agreement using the process described in the respective protocol." 42 C.F.R. 401.305(d)(1)-(2).

Parts A and B (Tolling of Deadline for Return)

The deadline for the *return* of overpayments will be suspended when:

OIG or CMS acknowledges receipt of a submission to the OIG Self-Disclosure Protocol or CMS Voluntary Self-Referral Disclosure Protocol, respectively, and will remain suspended until such time as a settlement agreement is entered, the person withdraws from the protocol or the person is removed from the protocol.

42 C.F.R. 401.305(b)(2)

Parts A and B (Enforcement and Look-Back)

Any overpayment retained by a person after the deadline for reporting and returning is an "obligation" for purposes of the FCA.

Any overpayment must be reported and returned if a person identifies an overpayment within 6 years of the date it was received.

42 C.F.R. 401.305(e)-(f).

US ex rel. Kane v. Continuum, No. 11 Civ. 2325 (ER)

Complaint-in-Intervention filed June 2014 against certain New York hospitals and Continuum, an operator of hospitals, for violating the reverse false claims provision of the FCA by failing to timely investigate and take steps to report and return potential overpayments from Medicaid.

US ex rel. Kane v. Continuum, No. 11 Civ. 2325 (ER) Allegations

In 2009, a glitch in the software used by Healthfirst, providing managed care insurance for Medicaid-eligible enrollees, caused Healthfirst to send remittances to participating providers, erroneously informing them they could seek additional payment for their services from secondary payers such as Medicaid. This, in turn, resulted in providers in the Continuum system claiming and receiving Medicaid payments to which they were not entitled.

US ex rel. Kane v. Continuum, No. 11 Civ. 2325 (ER)
Allegations

In September 2010, the NYS Comptroller identified a small number of claims submitted by Continuum and notified Continuum that Medicaid had been wrongly billed.

Certain Continuum employees, including Kane, the whistleblower, worked to identify other claims affected by the glitch.

In early February 2011, Kane ultimately provided a spreadsheet with approximately 900 claims, totaling over \$1 million, that were affected by the glitch and that potentially resulted in an overpayment. This spreadsheet contained the vast majority of the overpayments caused by the glitch.

US ex rel. Kane v. Continuum, No. 11 Civ. 2325 (ER)
Allegations

February 8, 2011, Continuum terminated Kane and, according to the Complaint, did nothing further with Kane's spreadsheet of claims.

Over following year, the Comptroller continued to analyze Continuum's billing and identified several additional tranches of affected claims and from March 2011 to February 2012 brought these additional claims to Continuum's attention.

US ex rel. Kane v. Continuum, No. 11 Civ. 2325 (ER) Allegations

Continuum proceeded to repay only small batches of affected claims.

Continuum never brought Kane's analysis to the attention of the Comptroller.

US ex rel. Kane v. Continuum, No. 11 Civ. 2325 (ER) Allegations

Final repayments were not made until March 2013 – more than two years after Kane provided the spreadsheet.

Repayments were made for more than 300 of the claims only after the Government issued a Civil Investigative Demand to Continuum concerning these payments in June 2012. US ex rel. Kane v. Continuum, No. 11 Civ. 2325 (ER)

The Government alleged that this conduct violated the "reverse false claims" provision of the FCA, 31 U.S.C. sec. 3729(a)(1)(G), and sought treble damages, plus an \$11,000 penalty for each overpayment retained in violation of the FCA.

United States ex rel. Kane v. Healthfirst, Inc., 120 F. Supp. 3d 370 (S.D.N.Y. 2015)

Court found the complaint pled an "obligation" under the FCA, rejecting defendants' argument that Kane's list of claims had not "identified" overpayments, thus starting the 60-day clock.

Court adopted the Government's proffered "reasonable diligence" standard.

United States ex rel. Kane v. Healthfirst, Inc., 120 F. Supp. 3d 370 (S.D.N.Y. 2015)

Court ruled that "identified" has no "plain meaning" and construed it to mean "when a provider is put on notice of a potential overpayment," and noted that the amount of an obligation need not be "fixed" for a duty to repay to accrue under the statute.

Court found that using a "conclusively establish" standard would create a "perverse incentive" for the provider to delay.

Kane Settlement

Entered by Court August 24, 2016.

Overpayments – approximately \$800,000.

Total Settlement Amount -- \$2.95 million.

Pediatric Services of America

August 4, 2015 – day after Kane opinion – DOJ settlement with Pediatric Services was announced:

"This is the first settlement under the False Claims Act involving a health care provider's failure to investigate credit balances on its books to determine whether they resulted from overpayments made by a federal health care program. . . . "

"PSA had been maintaining numerous credit balances on its books that related to claims it had submitted to various federal health care programs, some of which had been on PSA's books for several years. Additionally PSA wrote off and absorbed credit balances that had resulted from overpayments into their revenue because they had not investigated the reason for the credit balances before doing so."

Department of Justice, Press Release (August 4, 2015)

Pediatric Services of America

Settlement Amount - \$6.88 million

OIG Corporate Integrity Agreement and included provisions directly related to conduct underlying the reverse false claim. *See* OIG-CIA at 13-14 and (Repayments of Overpayments) and Appendix C (Overpayment Review).