MEDICARE ADVANTAGE PLAN LITIGATION CHALLENGES CMS INTERPRETATION OF 60-DAY OVERPAYMENT RULE

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Despite years of being promised clarity and consistency in how the 60-Day Overpayment Rule ("60-Day Rule") would be applied to Medicare and Medicaid, providers still face different standards for reporting and returning overpayments depending on the government program involved, as well as possible fraud exposure for conduct that may not satisfy the long-standing "knowledge" requirement of the False Claims Act ("FCA"). Passed by Congress in the Patient Protection and Affordable Care Act of 2010 ("PPACA"), the 60-Day Rule imposed a new obligation on Medicare and Medicaid providers to report and return overpayments within limited timeframes, or face liability under the FCA for failure to do so. The statute and subsequent implementing regulations continue to cause confusion and anxiety as the 60-Day Rule's scope shifted and expanded through agency rule-making and federal court decisions seeking to fill in gaps in the rule-making.

In an effort to impose clarity on these issues as they apply to Medicare Advantage providers, UnitedHealthcare Insurance Company and its Medicare Advantage plans (collectively, "UHC") initiated a must-watch declaratory judgment action against the United States under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A) and (C), to square agency rulemaking under PPACA with the FCA's "knowledge" requirement, among other issues.[1] The United States unsuccessfully sought an early dismissal of the case and instead received an unfavorable district court ruling recognizing the potential validity of UHC's concerns.[2] Judicial review in this APA case based on an administrative record of the regulations at issue has moved forward to summary judgment. This article sets out the battle lines between UHC and the government in the declaratory injunction case. The article also briefly addresses the issue overlap with two FCA cases brought by the U.S. Department of Justice ("DOJ") in the Central District of California.[3]

But first, a review of the current regulatory requirements and how the government got there.

Background

The 60-Day Rule establishes a duty on providers to report and return any "overpayment" by the later of 60 days after the overpayment was "identified" or, if applicable, the date any corresponding cost report is due.[4] "Overpayment" is defined by PPACA as "any funds that a person receives or retains under [Medicare or Medicaid] to which the person, after applicable reconciliation, is not entitled."[5] The government programs at issue are Medicare Part A (hospital insurance), Part B (medical insurance), Part C (Medicare Advantage ("MA") organizations), Part D (prescription drug coverage), and Medicaid.[6]

The 60-Day Rule incorporates the FCA's enforcement scheme by defining an overpayment not timely reported and returned as an "obligation" for which a provider is liable for FCA civil damages and penalties, typically under a "reverse" false claims theory.[7] Providers are understandably concerned about the scope and interpretation of "overpayment," given that failure to return an identified overpayment within 60 days can have serious consequences – fraud litigation exposure, highly punitive treble damages and civil penalties, and potential exclusion from participation in federal healthcare programs.

PPACA did not specify what it means to "identify" an overpayment for purposes of starting the 60-day clock for repayment. In response to uncertainty as to when the obligation to repay starts, the Centers for Medicare & Medicaid Services ("CMS") committed to providing program-specific guidance regarding the application of the 60-Day Rule. CMS published a final rule applicable to Medicare Parts C and D in 2014 and to Medicare Parts A and B in 2016, both of which addressed the meaning of an "identified" overpayment. In 2015 case law emerged addressing the applicability of the 60-Day Rule to Medicaid providers.

The different rules applicable in each context, discussed further below, are summarized for ease of reference in the chart on the following page.

Medicare Parts C and D

In May 2014, CMS finalized the first of these rules, publishing a final rule applicable to Medicare Parts C and D ("Part C/D Final Rule").[8] The Part C/D Final Rule defined "identified" to include situations in which an MA plan or Part D sponsor "*has determined, or should have determined through the exercise of reasonable diligence* that [it] has received an overpayment."[9] This articulation of an "identified" overpayment was a departure from CMS's January 2014 proposed rule, which tracked the FCA knowledge requirement and stated that a payment was "identified" when the organization "has *actual knowledge of the existence of the overpayment or acts in reckless*

PAYOR	RULE REGARDING "IDENTIFYING" AN OVERPAYMENT
Medicare Parts C & D	A Medicare Advantage organization or Plan D sponsor has "identified" an overpayment when it "has determined, or should have determined through the exercise of reasonable diligence that [it] has **received** an overpayment." (emphasis added)
Medicaid	No CMS rule proposed, but one federal court found a Medicaid provider's overpayment is "identified" when the provider has been **put on notice** of a **potential** overpayment.
Medicare Parts A & B	A Part A/B provider has "identified" an overpayment when it "has, or should have through the exercise of reasonable diligence, determined that [it] has **received** an overpayment **and quantified the amount of the overpayment.**" (emphasis added)

disregard or deliberate ignorance of the existence of the overpayment."[10]

CMS did not explain why it shifted to a negligence-based mental state – *has determined or should have determined through the exercise of reasonable diligence* – for defining overpayments when negligence is not within the FCA's long-established knowledge requirement of actual knowledge, deliberate ignorance, or reckless disregard of the truth or falsity of information.[11] The Part C/D Final Rule Preamble states that MA plans and Part D sponsors have an existing obligation to submit accurate, complete, and truthful risk adjustment data under certification requirements, and CMS has always expected them to conduct payment evaluation procedures to meet the requirements of certifying the data.[12] Similarly, in CMS's response to providers seeking clarification of the meaning of reckless disregard and deliberate ignorance, CMS explained that "reasonable diligence" comprised of proactive compliance reviews is simply the "flip side" of the agency's long-standing requirement that providers submit complete, accurate, and truthful data and does not impermissibly lower the FCA knowledge standard to negligence.[13]

CMS, in effect, grafts the PPACA "overpayment" provision onto pre-existing regulatory requirements developed as part of the implementation of the Medicare+Choice (now MA) program, even though nothing in PPACA or its legislative history suggests this was the intended interpretation of "overpayment." By arguing that there is nothing new in its interpretation, CMS avoids a new notice and comment period for agency rule-making as required by the APA. Whether it has properly done so will be decided in the first instance in the UHC federal court litigation.

Medicaid

Limited federal case law developed in the FCA context has examined the issue of when the 60-day clock for overpayments begins to run for Medicaid claims, with the principle case decided in 2015 by the U.S. District Court for the Southern District of New York. In *United States ex rel. Kane v. Continuum Health Partners*,[14] the court held that the 60-day clock starts to run after the provider receives *notice of a potential overpayment*. Continuum Health Partners ("Continuum"), an owner and operator of non-profit hospitals, had inaccurately billed Medicaid as a secondary payor when its managed care organization had already received fixed payments for the services provided. The New York State Comptroller's office raised the issue to Continuum, which assigned a team, including the relator,[15] to review its billing data. The relator subsequently sent Continuum management an email attaching a spreadsheet of more than 900 potential billing errors, explaining that further analysis was needed to confirm the accuracy of the findings.[16] Four days after sending the spreadsheet to management, the relator was terminated; 60 days after he sent the spreadsheet, he filed a *qui tam* case. The government intervened after the Part C/D Final Rule was announced.

Continuum moved to dismiss, arguing that the United States failed to state a claim because Continuum had not *identified any overpayments* on the date it received relator's spreadsheet. The district court disagreed, holding that "identified" is when a provider is put on *notice of a potential overpayment*, not when an error is conclusively established.[17] The court, acknowledging that its holding imposed an "unforgiving" timeline on providers, reasoned that the FCA's legislative history suggested that Congress intended for FCA liability to attach where there is an established duty to pay money to the government, even if the precise amount due has not yet been determined.[18] The court noted that CMS had not issued regulations providing guidance to Medicaid providers, but found that its interpretation of "identified" was consistent with the Part C/D Final Rule and the proposed rule for Part A/B providers.[19]

Kane, though limited in precedential effect, is the most significant decision to date that analyzes the 60-Day Rule responsibilities of Medicaid providers.

Medicare Parts A and B

On February 12, 2016, four years after its proposed rule was published, CMS issued the long-awaited Final

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Rule for Medicare Part A and B providers ("Part A/B Final Rule"), which added some clarification to the requirements for reporting and returning Part A and B overpayments, possibly in response to provider concerns about the Part C/D Final Rule and *Kane* Medicaid decision.[20] The Part A/B Final Rule states 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*."[21] CMS explicitly states that "reasonable diligence" means both "proactive compliance activities" to check for overpayments and "reactive reviews" (*i.e.*, investigations upon receipt of "credible information" of an overpayment) of Medicare claims.[22] For Part A/B providers, the 60-day clock begins to run after the reasonable diligence period, which CMS explained may take "at most 6 months from the receipt of credible information, absent extraordinary circumstances."[23] Providers, accordingly, have up to eight months for repayment (six months to investigate, plus 60 days to report and return the overpayment). But if the provider has credible information that an overpayment occurred and does not exercise reasonable diligence, the provider will not be afforded six months to investigate and any overpayment will be considered late after 60 days.[24]

UHC Declaratory Injunction Litigation

In the midst of these evolving standards, in January 2016 UHC filed a declaratory injunction action against CMS in the U.S. District Court for the District of Columbia seeking relief under the APA. UHC's complaints about the Part C/D Final Rule fall into two buckets – (1) the rule imposes FCA liability for reverse false claims based on a negligence standard not included in the FCA's knowledge requirement, and (2) the rule violates the statutory mandate of actuarial equivalence between traditional Medicare Fee-for-Service ("FFS") plans and MA plans.

UHC's Allegations

Negligence Standard

UHC alleges that the Final Rule applies a negligence standard for FCA liability by specifying that an overpayment would be considered "identified" when a MA plan determined, *or should have determined through reasonable diligence*, that it had received an overpayment.[25] According to UHC, "should have identified through the exercise of reasonable diligence" (*i.e.*, negligence) is a new standard not contemplated by PPACA or the FCA, which contain a recklessness standard.[26] UHC also contends that this negligence standard exceeds CMS's statutory authority under the APA[27] and is procedurally deficient because it was not a logical outgrowth of the proposed rule, which incorporated a "reckless disregard or deliberate ignorance" standard.[28]

Actuarial Equivalence

UHC devotes much of the Complaint to arguing that the Part C/D Final Rule violates the statutory requirement that MA plans be treated with "actuarial equivalence."[29] As background, MA plans are compensated for the risk they assume in insuring health plan members.[30] Congress requires Medicare to calculate reimbursement for MA plan beneficiaries using the same methodology as it does for Medicare FFS plan beneficiaries.[31] To accomplish this objective (known as actuarial equivalence), CMS first calculates the average monthly expenditure for the average Medicare FFS beneficiary. It then adjusts these baseline repayments according to the beneficiary profile of particular MA plans. Adjustments are based on MA plan data provided to CMS of diagnostic codes from physician medical records.[32] MA plans are required to certify "based on best knowledge, information, and belief" that the risk adjustment data they provide to CMS, including diagnostic codes, are accurate.[33] Despite this requirement, the Complaint alleges that CMS has not previously required MA plans to independently validate diagnosis codes. Instead, CMS had created a risk adjustment model for MA plans, which was built using unaudited FFS data, to account for anticipated errors in diagnosis codes in the MA plan data.[34]

UHC alleges that the Part C/D Final Rule violates the requirement of actuarial equivalence because it requires MA plans to independently verify diagnostic codes provided by third parties (physicians) and delete those unsupported in the medical records. UHC argues that the Rule requires MA plans for the first time to scrutinize and correct enrollee data (such as those diagnostic codes from physicians) used to establish CMS per patient, per month payment rates to the MA plans, and it puts MA plans at the risk of incurring FCA exposure if it fails to do so for each inaccurate entry.[35] The net effect, according to UHC, is that by imposing greater scrutiny on MA plans than CMS applies to its own enrollee data for FFS plans, CMS will systematically underpay for the care of MA beneficiaries.[36]

UHC Survives Motion to Dismiss

CMS moved to dismiss the Complaint, arguing that UHC lacked standing and the court lacked subject matter jurisdiction. On March 31, 2017, the district court denied CMS's motion, in large part because of the new Rule's potential FCA impact.[37] In ruling on UHC's standing to challenge the Part C/D Final Rule, the court had to first determine whether UHC was allegedly injured either because the rule imposed a *novel* or new legal obligation on UHC or it

simply restated *pre-existing* obligations.[38] The court acknowledged that MA plans are obligated to exercise "due diligence" to certify to the accuracy of risk adjustment data they submit to CMS under 42 C.F.R. § 422.504(l)(2) and that they are required to adopt effective compliance programs under 42 C.F.R. § 422.503(b)(4)(v).[39] The court disagreed, however, that the PPACA overpayment provision imposed a pre-existing obligation on MA plans to engage in due diligence of diagnostic codes entered in medical records.[40] The court focused on the Rule's requirement that MA plans engage in "reasonable diligence," which requires "at a minimum . . . proactive compliance activities conducted in good faith by qualified individuals to monitor the receipt of overpayments."[41] The court found the new requirement's impact on potential FCA liability to be significant:

> While the Secretary points to other requirements that [UHC] must exercise "due diligence," CMS has pointed to no other regulations where the statute has been interpreted to apply such a standard, either to CMS or to Medicare Advantage insurers. *In essence, the Secretary would have the Court find that the CMS Rule's insistence on 'proactive compliance activities,' under pain of a False Claims Act suit provable by negligence alone is meaningless. It is not; it imposes (for good reason or not) new obligations.*[42]

Key Issues at Summary Judgment

As directed by the court, UHC and CMS briefed cross-motions for summary judgment, which likely will be decided later in 2018.[43] The vast majority of the briefing detailed the workings of Medicare Part C from the viewpoints of UHC, as a Part C provider, and CMS, the regulator. The parties differ on two key points – whether complete and accurate medical records are necessary to determine an MA plan's actuarial equivalence to a FFS provider and whether a negligence standard has been incorporated into FCA violations for overpayments by the Part C/D Final Rule. This article focuses on the negligence issue because it has important implications for a broader audience – all Medicare and Medicaid providers subject to FCA liability for not timely returning overpayments – but also briefly summarizes the actuarial equivalence arguments.

Negligence as a Basis for FCA Liability

– UHC

UHC argues that CMS essentially pulled a "surprise switcheroo" by publishing a final rule requiring MA plans to return overpayments that were "identified" and those that "should have been identified" or be subject to potential FCA treble damages and penalties. UHC also contends that even if the public had been given an opportunity to provide comments on the "should have been identified" standard, it is inconsistent with PPACA's legislative history and an unreasonable interpretation of the statutory text requiring overpayments to be "identified."[44] UHC builds on the district court's earlier comment in its denial of CMS's motion to dismiss that the "should have been identified" language is a negligence standard not found in the FCA.[45]

First, UHC emphasizes that the plain and unambiguous definition of "identified" requires actual knowledge, not negligence.[46] UHC provides several noted dictionary definitions of "identified," all of which use terms such as "determine," "establish," or even "indicate," and none of which suggest that "identified" means "should have" determined, established, or indicated.[47]

Second, UHC contends that, even if the word "identified" was ambiguous, CMS's interpretation incorporating negligence is unreasonable given PPACA's legislative history and the well-established scope of FCA liability.[48] UHC reviews the House and Senate versions of PPACA to demonstrate that the final legislation, adopting the Senate version, reflected Congress's intent that the standard for "identify" was to be stricter, not looser, than the FCA's knowledge requirement of actual knowledge, recklessness, or willful blindness.[49] According to UHC, the House's initial version of PPACA's overpayment provision required an overpayment to be reported within 60 days after it was *known*, which was to have the same meaning as the FCA's knowledge standard.[50] UHC notes that the Senate version, ultimately adopted by Congress, substituted "identified" for "known," reflecting Congress's decision to require actual knowledge, not the more expansive FCA knowledge standard.[51] In no event, though, did Congress in PPACA incorporate a lesser negligence standard.

UHC goes on to argue that its interpretation of Congress's intent is supported by its consistency with FCA case law that requires more than negligence for FCA liability to be found.[52] UHC states "[u]nder CMS's new definition, MA plans potentially are subject to this punitive liability based on merely negligent *inaction* (*i.e.*, failing to proactively search for and find overpayments) – a stark departure from the normal rule that the False Claims Act does *not* allow liability based only on negligence."[53]

Lastly, UHC objects that CMS violated the APA when it proposed a definition of "identified" in its proposed rule and then applied a significantly different definition in its final rule – the "surprise switcheroo" – without the required notice and comment period.[54]

– CMS

CMS's approach to UHC's argument regarding the new imposition of a negligence standard in the Part C/D Final Rule is to deny that "should have been identified" is a negligence standard; instead CMS asserts that the standard of "should have been identified through the exercise of reasonable

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diligence" is the same as reckless disregard under the FCA.[55] By doing so, CMS inexplicably ignores the district court's prior finding that "should have been" is a negligence standard. CMS also ignores that UHC argued that "identified" could mean actual knowledge, a higher standard than FCA knowledge incorporating reckless disregard.

Instead of addressing the "should have been identified" language of the Part C/D Final Rule, CMS discusses only the "reasonable diligence" portion of the rule requiring an MA plan to return an overpayment when it "has determined, or should have determined through the exercise of reasonable diligence that [it] has received an overpayment."[56] CMS first states, seemingly without statutory authority, that the Part C/D Final Rule's use of "reasonable diligence" incorporates the preexisting duty of MA plans to undertake "due diligence" in submitting accurate, complete, and truthful encounter data under 42 C.F.R. § 422.504(l) (an implementing regulation of the Medicare+Choice program).[57] CMS then equates "reasonable diligence" in the overpayment regulation with "due diligence" under § 422.504(l) and, thereby, concludes that there has been no "surprise switcheroo" between the proposed rule and the final rule.[58]

Finally, again brushing aside UHC's contention that the overpayment requirement's "should have been identified" standard is a negligence standard, CMS cites the previously-discussed *Medicaid* FCA case – *Kane* – for the proposition that Congress intended "to subject willful ignorance of Medi[care] overpayments to the [False Claims Act's] stringent penalty scheme."[59]

Kane, however, may not be as supportive as CMS suggests. First, *Kane* is a Medicaid case, and the court's ruling expressly applied to Medicaid overpayments. Second, CMS's substitution of the word *Medicare* for *Medicaid* in a key quotation from the case was done without explanation or qualification, in contrast to an explicit admonition by the *Kane* court about the limits of its look to Medicare standards for deciding a Medicaid case.[60] Third, CMS did not offer context for the dispute in *Kane* – defendants were asserting that actual knowledge was required for FCA liability, whereas DOJ asserted that willful ignorance applied. The court sided with DOJ but, importantly, *Kane* did not involve application of the "should have identified" standard to proactive compliance activities (such as those that the District of Columbia court expressed concern about in rejecting the government's motion to dismiss). The exact opposite was true. *Kane* was a reactive situation – a provider was on notice of potential Medicaid overpayments but failed to take timely action to report and return the overpayments. With that backdrop, CMS's reliance on the "willful ignorance" language in *Kane* may be misplaced at its peril.

Actuarial Equivalence

– UHC

UHC's summary judgment briefing largely addresses its actuarial equivalence claim that CMS is required by statute to ensure that payments to MA plans are adjusted "using an apples-to-apples" comparison of the risk assumed by a MA plan in insuring a beneficiary and the risk that CMS incurs for an identical FFS beneficiary.[61] UHC argues that the Part C/D Final Rule's interpretation of "overpayment" violates the MA statutory requirements "by measuring the health status of MA plan beneficiaries using one measure (diagnoses recorded in medical charts) and the health status of FFS beneficiaries using another (diagnosis codes in claims data), in a manner that produces different assessments of risk for identical patients."[62]

– CMS

CMS frames UHC's arguments as a blatant attempt to get paid for beneficiary healthcare claims that are not supported in the underlying medical charts.[63] CMS lays out a starkly different understanding of the requirements of actuarial equivalence, and CMS argues that interpreting claims for payment based on diagnoses unsupported by beneficiary medical records as "overpayments" is reasonable and not contrary to the requirements of "actuarial equivalence" or of using the same methodology to calculate the risk score for traditional Medicare beneficiaries as for MA plan beneficiaries.

As a preliminary point, CMS argues that defining "overpayment" to include claims for payment based on diagnoses unsupported by the medical record is plainly reasonable, given its long requirement that diagnosis codes be supported by medical records, as expressed in MA Program Manuals, training materials, and the certification requirement in 42 C.F.R. § 422.504(l) (2).[64] CMS claims that the Part C/D Final Rule did not change this underlying requirement, and that challenging the Part C/D Final Rule will not relieve MA plans of this obligation.[65]

CMS claims that UHC has fabricated a risk adjustment model that bears no resemblance to the one CMS created. It denies having created a system built on an acknowledgment that MA risk adjustment data contained numerous erroneous risk adjustment codes.[66] It further asserts that CMS has a complex process for ensuring actuarial equivalence, and that the court should defer to its expertise in this context, consistent with the broad discretion given to the agency under the MA statute.[67]

California False Claims Act Cases

Prior to UHC filing its declaratory injunction action, DOJ unsealed and joined two whistleblower FCA

cases in California against UHC entities (and others) alleging, *inter alia*, overpayments arising from risk adjustment data that did not accurately reflect the health risk of patients due to inadequately documented diagnosis codes in medical records and false attestations of accuracy and truthfulness regarding risk adjustment data sent to CMS.[68]

Of current significance is *United States ex rel. Poehling v. UnitedHealth Group*,[69] which was significantly trimmed back by the Central District of California on February 12, 2018 to leave only the "reverse" FCA claims[70] for overpayments relating to the risk adjustment data. The *Poehling* court found that the false attestation claims did not pass the Supreme Court's *Escobar* materiality test[71] because the complaint failed to allege that if CMS knew of the false attestation, defendants' risk adjustment payments would have changed.[72] By contrast, and potentially opening a new front in FCA cases, the court refused to find that *Escobar*'s materiality bar applied to this "reverse" false claim arising from an overpayment because (1) *Escobar* addressed the typical false presentment of a false or fraudulent claim brought under 31 U.S.C. § 3729(a)(1)(A), (2) the Ninth Circuit had previously held that provider cost reports were material because they had the effect of increasing or decreasing a defendant's overpayment obligation, and (3) the government had sufficiently alleged materiality in its "reverse" false claims allegations.[73] Although the court dismissed the false attestation claims with leave to amend, DOJ on February 26, 2018 advised the court that its complaint would not be further amended, leaving it to proceed with the overpayment claims only.[74]

Conclusion

Clearly, the two district courts involved in the UHC declaratory injunction and remaining FCA case have their work cut out for them. Applying standards for statutory and regulatory interpretation and the APA, the court in the District of Columbia will decide whether CMS's Part C/D Final Rule exceeds its statutory authority. Meanwhile, the court in the Central District of California, applying a preponderance of the evidence standard,[75] will likely need to decide whether risk adjustment data may contain inaccurate diagnosis codes and, if so, then has DOJ been able to demonstrate that all elements of the FCA are met, particularly defendants' knowledge of the inaccurate codes. The Central District may wait for the District of Columbia to rule on the declaratory injunction before deciding the first issue.

The other issue before the District of Columbia court – whether "should have been determined through reasonable diligence" is a negligence state of mind – may be a foregone conclusion, given its earlier decision and CMS's disregard of the court's expression of concern about potential FCA liability for proactive compliance activities.

In any event, MA plans and other Medicare/Medicaid providers will be watching both litigation fronts closely.

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Endnotes

1 *UnitedHealthcare Ins. Co. v. Azar*, No. 1:16-cv-00157-RMC (D.D.C., filed Jan. 29, 2016), Complaint ("Compl."), ECF No. 1.

2 *UnitedHealthcare Ins. Co. v. Azar*, 248 F. Supp. 3d 192 (D.D.C. 2017).

3 *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, No. CV 16-08697 (C.D. Cal., transferred Nov. 8, 2016 from W.D.N.Y., filed Mar. 24, 2011); *United States ex rel. Swoben v. Scan Health Plan*, CV-09-5013 (C.D. Cal., filed Jul. 13, 2009).

4 42 U.S.C. § 1320a-7k(d)(2).

5 42 U.S.C. § 1320a-7k(d)(4)(B).

6 The PPACA 60-day Overpayment Rule does not apply to TRICARE or the Department of Veterans Affairs (the "VA"). However, TRICARE and the VA are subject to FCA liability under the "reverse false claims" provisions for retaining overpayments. *See* 31 U.S.C. § 3729(a)(1)(G) (creating FCA liability for avoiding an obligation to pay money to the government); 31 U.S.C. § 3729(b)(3) (defining an "obligation" to include retention of an overpayment). At least one healthcare provider has entered into a settlement with DOJ to resolve allegations that the provider failed to report and return overpayments from various federal payors, including TRICARE and the VA, as well as Medicare and Medicaid. *See* Press Release, Department of Justice, "Jacksonville Cardiovascular Practice Agrees to Pay more than $440,000 to Resolve False Claims Act Allegations for Failing to Reimburse Government Health Care Programs," (Oct. 13, 2017), https://www.justice.gov/usao-mdfl/pr/jacksonville-cardiovascular-practice-agrees-pay-more-440000-resolve-false-claims-act.

7 42 U.S.C. § 1320a-7k(d)(3); 31 U.S.C. § 3729(b)(3)).

8 2015 *Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefits Programs*, 79 Fed. Reg. 29,844-29,968 (May 23, 2014) (codified in pertinent part at 42 C.F.R. § 422.326).

9 42 C.F.R. §§ 422.326(c), 423.360(c) (emphasis added). Note that in the Part C context, MA plans do not submit claims for services. Rather, they submit risk adjustment data composed of diagnosis codes for their beneficiaries in a given year that are included in CMS's calculation of monthly per-beneficiary sums. *See* 42 U.S.C. § 1395w-23(a)(1)(A), (C)(i). Thus, in the Part C context, an overpayment

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would include retention of a monthly payment not supported by diagnosis codes.

10 2015 *Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefits Programs*, 79 Fed. Reg. 1918, 2055, 2066 (as proposed Jan. 10, 2014) (emphasis added).

11 *See* 31 U.S.C. § 3729(b)(1)(A).

12 79 Fed. Reg. 29,923 (citing 42 C.F.R. §§ 422.504(l) and 423.505(k)).

13 79 Fed. Reg. 29,923-24.

14 *United States ex rel. Kane v. Continuum Health Partners, Inc., et al.*, 120 F. Supp. 3d 370 (S.D.N.Y. 2015) ("*Kane*").

15 A "relator" is a private plaintiff who is permitted to bring a civil fraud action on behalf of the United States under the FCA. After an opportunity to investigate the relator's allegations, DOJ may intervene and proceed with the action or it may decline to proceed, in which case the relator may continue the case on behalf of the United States. *See* 31 U.S.C. § 3730(b).

16 *Id.* at 375-77.

17 *Id.* at 388.

18 *Id.* at 388-89.

19 *Id.* at 392-93. The court pointed to CMS's February 16, 2012 proposed Part A/B rule, stating that an overpayment is "identified" when the provider "has actual knowledge of the overpayment or acts in reckless disregard or deliberate ignorance of the payment." *Reporting and Returning of Overpayments*, 77 Fed. Reg. 9179, 9187 (as proposed Feb. 16, 2012). This standard was changed in the Part A/B Final Rule, as discussed *infra.*).

20 *Reporting and Returning of Overpayments*, 81 Fed. Reg. 7654-7684 (Feb. 12, 2016) (codified at 42 C.F.R. pt. 401 and 405).

21 42 C.F.R. § 401.305(a)(2) (emphasis added).

22 81 Fed. Reg. at 7662.

23 *Id.*

24 81 Fed. Reg. 7662-63.

25 Compl. at ¶¶ 77-78 (emphasis added); 79 Fed. Reg. 29,923.

26 Compl. at ¶¶ 5, 78, 95; 31 U.S.C. § 3729(b)(1) (defining "knowing" and "knowingly").

27 5 U.S.C. § 706(2)(A) and (C).

28 Compl. at ¶ 96.

29 Compl. at ¶¶ 6-10.

30 Compl. at ¶ 30.

31 Compl. at ¶¶ 31-33.

32 Compl. at ¶¶ 30-34.

33 Compl. at ¶ 41 (citing 42 C.F.R. §§ 422.504(l)(2)).

34 Compl. at ¶ 42-43.

35 Compl. at ¶¶ 42, 52, 77-78.

36 Compl. at ¶¶ 78, 80-81.

37 *UnitedHealthcare*, 248 F. Supp. 3d 192 at 205.

38 *Id.* at 200.

39 *Id.* at 200-01. Both regulations address requirements for contracts between MA plans and CMS and predate the 60-Day Rule.

40 *Id.*

41 *Id.* at 201 (citing 79 Fed. Reg. at 29,923).

42 *Id.* (emphasis added).

43 UHC Motion for Summary Judgment and Supporting Memorandum ("UHC MSJ") (filed Oct. 17, 2017), ECF No. 47-1; CMS Cross-Motion for Summary Judgment and Opposition to Plaintiff's Motion for Summary Judgment ("CMS Opp.") (filed Dec. 4, 2017), ECF No. 58; UHC Memorandum in Opposition to Cross Motion for Summary Judgment ("UHC Reply") (filed January 18, 2018), ECF No. 60; CMS Reply in support of Cross Motion for Summary Judgment ("CMS Reply") (filed February 12, 2018), ECF No. 64.

44 UHC MSJ at 42-44.

45 *Id.*

46 *Id.* at 42-43.

47 *Id.*

48 *Id.* at 43.

49 *Id.*

50 *Id.* (citing H.R. 3200, 111th Cong. § 1641).

51 *Id.* (citing Pub. L. No. 111-148, § 6402(a), 124 Stat. at 755).

52 *Id.* at 43-44.

53 *Id.* at 44 (citations omitted) (emphasis in original).

54 *Id.* at 44-45.

55 CMS Opp. at 43-45.

56 *Id.* at 43-44; 42 C.F.R. § 422.326(c).

57 *Id.* at 44.

58 *Id.*

59 *Id.* (citing *Kane*, 120 F. Supp. 3d at 391).

60 The *Kane* court looked to Medicare regulations in considering the reasonableness of its outcome in the Medicaid context, but it also stated that it "considers" but "does not place significant weight on the interpretation" provided by CMS. 120 F. Supp. 3d at 391.

61 UHC MSJ at 1-2 (citing 42 U.S.C. § 1395w-23(a)(1)(C)(i)).

62 UHC MSJ at 12, 21, 27, 27-32. UHC explains the impact on the MA plan in the following example:

> Suppose that when it calibrates the [risk adjustment model], CMS identifies four FFS beneficiaries with the diagnosis code for diabetes and determines that the aggregate incremental healthcare costs for the four beneficiaries the following year were $12,000. CMS therefore concludes that the average per-patient cost associated with diabetes is $3,000 and it sets the diabetes risk coefficient accordingly. But suppose further that one of these diagnosis codes was a false positive; the beneficiary did not in fact have diabetes. That means that the $12,000 was in reality attributable to just three beneficiaries, such that the true per-patient cost of diabetes was actually $4000 ($12,000 ÷ 3 beneficiaries). By averaging the cost over the four beneficiaries with the diagnosis code, rather than just the three beneficiaries who actually have diabetes, CMS's model produces a lower average incremental cost (and associated risk coefficient) than it would have done if the diagnosis codes in the FFS data had been perfectly accurate. . . . If all beneficiaries actually have diabetes, this payment will undercompensate the plan for its presumptive incremental costs, which would be $16,000 ($4,000 per beneficiary who actually has diabetes).
>
> UHC MSJ at 12.

63 *See, e.g.*, CMS Opp. at 24 ("But United has concocted an alternative history, in which payment on the basis of unsubstantiated diagnoses is an essential premise of everything the Secretary has done to implement the Medicare Advantage program, which the Overpayment Rule would now abruptly and arbitrarily abandon. . . . What United wants is not the vacatur of 42 C.F.R. 422.326, which it barely mentions in its brief, but something far more wide-reaching: a judicial declaration that Medicare Advantage insurers can lawfully claim payments for the costs associated with diseases their beneficiaries do not have.").

64 CMS Opp. at 24-27.

65 CMS Opp. at 2-3.

66 CMS Opp. at 1-2, 8-13.

67 CMS Opp. at 14-20, 28-31, 36-40; 42 U.S.C. § 1395w-23(a)(1)(C)(i) ("The Secretary shall adjust the payment amount . . . for such risk factors as age, disability status, gender, institutional status, *and such other factors as the Secretary determines to be appropriate*, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence.") (emphasis supplied).

68 One case, *United States ex rel. Swoben v. Scan Health Plan*, CV-09-5013 (C.D. Cal., filed Jul. 13, 2009), was dismissed by the government on November 2, 2017 after eight years of investigation and litigation when the government chose not to further amend its complaint-in-partial-intervention after the court dismissed significant portions of its claims.

69 *United States ex rel. Poehling v. UnitedHealth Group, Inc.*, No. CV 16-08697 (C.D. Cal., transferred Nov. 8, 2016 from W.D.N.Y., filed Mar. 24, 2011).

70 *Id.*, Civil Minutes at 11 (entered Feb. 12, 2018), ECF No. 212 (citing 31 U.S.C. § 3729(a)(1)(G) (knowingly concealing or knowingly improperly avoiding an obligation to pay or transmit money to the government)).

71 *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1996, 2003-04 (2016). In *Escobar*, the Supreme Court held, *inter alia*, that only material noncompliance with statutes, regulations, or contract requirements can trigger FCA liability, and the government's payment of claims in full despite its

actual knowledge that certain requirements were violated is strong evidence that the requirements were not material.

72 *Poehling*, No. CV 16-08697, Civil Minutes at 16. *See also United States ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 764 (3d Cir. 2017) (upholding dismissal of *qui tam* complaint in Medicare Part D case where court found CMS would have paid defendant PBM's Part D claims containing "dummy prescriber IDs" even if it had known of their use).

73 *Id.*, Civil Minutes at 19-20 (citing, for the second point, *United States v. Bourseau*, 531 F.3d 1159 (9th Cir. 2008)).

74 *Id.*, United States' Notice of Decision Regarding Amendment of Complaint and Request for a Scheduling Conference (filed Feb. 28, 2018), ECF No. 217.

75 31 U.S.C. § 3731(d).

REMINDER:

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