Health Matrix: The Journal of Law-Medicine

Volume 31 | Issue 1 Article 8

2021

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APPLYING *ALLINA* TO THE WORLD OF *ESCOBAR*: AVOIDING "TRAPS, ZAPS, AND ZINGERS" IN MEDICARE FALSE CLAIMS ACT ACTIONS

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INTRODUCTION

In 2019, the U.S. Government spent 1.2 trillion dollars on health care, just under a third of total U.S. tax revenue.[1] Not surprisingly, fraud, waste, and abuse in U.S. healthcare spending are a major source of concern for the federal government, which has observed that: "Every year, the submission of false claims to the government cheats the American taxpayer out of billions of dollars . . . . In some cases, unscrupulous actors undermine federal healthcare programs or circumvent safeguards meant to protect the public health."[2] To protect the integrity of healthcare spending, the federal government relies heavily on the Federal False Claims Act ("FCA"), a federal-wide anti-fraud statute, to root out, punish, and deter fraud, waste, and abuse in the healthcare industry.[3] In 2019, the DOJ recovered $3.05 billion in FCA judgments and settlements, with $2.6 billion originating from health care and life sciences companies, including drug and medical device manufacturers, hospitals, and pharmacies.[4] It was the tenth

1. *Briefing Book*, TAX POL'Y CTR., https://www.taxpolicycenter.org/briefing-book/how-much-does-federal-government-spend-health-care [https://perma.cc/E2JQ-KM9Q] (last visited Dec. 3, 2019). In 2017, the U.S. government spent even more on healthcare – 1.2 trillion dollars. *See National Health Expenditures 2017 Highlights*, CMS.GOV, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-andReports/NationalHealthExpendData/Downloads/highlights.pdf [https://perma.cc/S24S-7ZEV] (last visited Oct. 4, 2020).

2. Press Release, U.S. Dep't of Justice, Justice Department Recovers Over $2.8 Billion from False Claims Act Cases in Fiscal Year 2018 (Dec. 21, 2018), https://www.justice.gov/opa/pr/justice-department-recovers-over-28-billion-false-claims-act-cases-fiscal-year-2018 [https://perma.cc/Q82R-CX3Y].

3. 31 U.S.C. § 3729 (2018).

4. Daniel Wilson, *Health Care Fraud Made Up Bulk of Feds' $3B Recovery in '19*, LAW360 (Jan. 9, 2020), https://www.law360.com/health/articles/1232891/health-care-fraud-made-up-bulk-of-feds-3b-recovery-in-19?nl_pk=e30108f0-7c42-4ac2-a58c-da552ddd24ef&utm_source=newsletter&utm_medium=email&utm_campaign=health&read_more=1&attachments=true [https://perma.cc/9TNY-YPGD].

consecutive year that health care-related judgments and settlements exceeded $2 billion.[5]

In recent years, a significant number of healthcare FCA cases have been predicated not on a theory that the defendant committed an overt act of fraud, but on assertions that, though the items or services for which claims were submitted were rendered, such items or services failed, in some way, to conform to the intricate web of Centers for Medicare and Medicaid Services ("CMS") regulations, rules, policies, guidance, commentary, and course of dealings that serve to signal to Medicare participants the terms of CMS's reimbursement.[6] These cases, which are brought under what is referred to as a theory of "legal falsity," have held that a claim may be false even though, on its face, it accurately describes the items or services delivered, if the claim was tainted by a violation of law such that the government, if aware of the violation, would not consider the claimant to have a right to reimbursement. As a result, the FCA has increasingly become a means to punish and deter not only conduct that is commonly understood to be fraudulent, but also a wide range of non-compliance with any number of healthcare rules and regulations and agency sub-regulatory guidance. While this expansion of the FCA has served an important role in the protection of the integrity of federal healthcare programs, courts have struggled to draw a coherent and consistent line between commonplace non-conformance with any number of CMS's innumerable programmatic rules and guidance, and violations that are significant enough to render a claim fraudulent. FCA cases have, therefore, been marred by a remarkable level of unpredictability as to whether and when the FCA may be deployed as a legitimate tool to deter and punish run-of-the-mill fraud, and when its use crosses the line into misuse as an all-purpose regulatory and breach of contract enforcement mechanism for federal healthcare programs.

In its pivotal 2016 opinion in *Universal Health Services, Inc. v. United States ex rel. Escobar*, the Supreme Court attempted to draw just such a line, when it sought to identify a meaningful distinction between mere non-compliance with program standards and fraud.[7] In an effort to unify years of inconsistent treatment of FCA cases by lower courts, the Court held that a legal falsity case must be based on a violation of "material" rules and regulations, compliance with which is a prerequisite to reimbursement, and not on immaterial rules and regulations that do not impact the government's willingness to pay a

5. *Id.*

6. See, e.g., the various Medicare manuals available at *Internet Only Manuals*, CMS.GOV, https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs [https://perma.cc/RFS8-58D5] (last visited Oct. 4, 2020).

7. *See* Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989 (2016).

claim.[8] Unfortunately, the resulting line, for reasons discussed in this article, has proven too difficult to apply with consistency. Judges, lawyers, whistleblowers, and members of the healthcare industry have been largely unsuccessful in bringing clarity, consistency and, ultimately, predictability to *Escobar*'s vague requirement that a violation of the FCA predicated on legal falsity requires a "material" misrepresentation of compliance with law.

In its 2019 decision in *Azar v. Allina Health Services*,[9] the Supreme Court addressed whether CMS, by simply posting an announcement on the CMS website, could implement a rule that affected hospitals' entitlement to Medicare reimbursement.[10] CMS argued that the rule at issue was interpretive, and, therefore, exempt from notice-and-comment requirements.[11] Affirming the D.C. Circuit's 2017 holding in *Allina v. Price*,[12] and breaking with most courts that had considered the question, the Supreme Court held, based on a largely textual analysis of the Medicare Act, that: (i) rules that have an impact on a right to payment are "substantive rules" under the Medicare Act, and (ii) the Medicare Act's procedural requirements do not contain an exception to notice-and-comment requirements for substantive interpretive rules.[13] In other words, the *Allina* court held that analysis of CMS rulemaking under the Medicare Act must diverge from traditional Administrative Procedure Act ("APA") analysis.[14] Specifically, the Court held that

8. *Id.* at 1994.

9. Azar v. Allina Health Servs., 139 S. Ct. 1804 (2019).

10. *Id.* at 1808.

11. *Id.* at 1805.

12. 863 F.3d 937 (D.C. Cir. 2017). The court held:

> [A]s relevant here, the Medicare Act requires notice-and-comment rulemaking for any (1) "rule, requirement, or other statement of policy" that (2) "establishes or changes" (3) a "substantive legal standard" that (4) governs "payment for services." All four requirements are readily met here . .. HHS argues that the Medicare Act incorporates the APA's exceptions to notice-and-comment requirements. According to HHS, even if the decision to include Part C days in the fiscal year 2012 Medicare fractions is a rule, it is at most an "interpretive rule" for purposes of the APA. As a result, it is exempt from the APA's—and, by extension, the Medicare Act's—notice-and-comment requirements. The problem with that argument is that the Medicare Act does not incorporate the APA's interpretive-rule exception to the notice-and-comment requirement.

Id. at 943–44.

13. *Allina,* 139 S. Ct. at 1811.

14. Prior to the D.C. Circuit Court's opinions in *Price* and *Clarian Health West, LLC v. Hargan*, 878 F.3d 346 (D.C. Cir. 2017), it appears that

under the Medicare Act, any change to, or issuance of, a "substantive legal standard" (other than one appearing in a National Coverage Determination ("NCD")) having an impact on payment under the Medicare program, must receive notice and public comment.[15]

Thus, whereas under the APA there are three categories of rules—legislative, interpretive, and procedural—with the latter two categories being excluded from the requirement of notice-and-comment rule making,[16] under the Medicare Act there would appear to be only two categories of rules: substantive (which may impact payment and must be adopted as regulations) and procedural (which may not impact a right to payment but may appear either in sub-regulatory guidance or be adopted as regulations).[17] Substantive interpretive rules, as such, simply do not exist in the world of Medicare reimbursement.[18] Consequently, in analyzing a healthcare program participant's right to payment, non-binding sub-regulatory guidance is not due the deference it would be afforded as an interpretive rule under the APA, as such deference is unique to, and dependent on, the establishment of that class of rules by Congress in the APA.[19] After *Allina*, rules that are

every court of appeals that had considered the issue held that that the Medicare Act incorporated the same exception for interpretive rules to notice-and-comment rulemaking as did the Administrative Procedure Act. Graham Haviland, *Not So Different after All: The Status of Interpretive Rules in the Medicare Act*, 85 U. OF CHI. L. REV. 1511, 1523 (2018). *See, e.g.,* Via Christi Reg'l Med. Ctr., Inc. v. Leavitt, 509 F.3d 1259, 1277 n.11 (10th Cir. 2007); Baptist Health v. Thompson, 458 F.3d 768, n.8 (8th Cir. 2006); Omni Manor Nursing Home v. Thompson, No. 04-3836, at 427, 428 (6th Cir. Oct. 11, 2005); Warder v. Shalala, 149 F.3d 73, 79 n.4 (1st Cir. 1998); *See also* Monmouth Med. Ctr. v. Thompson, 257 F.3d 807, 814 n.2 (D.C. Cir. 2001) (noting the question of whether the Medicare Act incorporates the APA's interpretive-rule exception, but not expressly deciding it).

15. *Allina*, 139 S. Ct. at 1812, 1814.

16. 5 U.S.C. § 553(b)(3)(A) (2018) (exempting from the notice-and-comment process rules, among others, involving "rules of agency organization, procedure, or practice" and interpretative rules and general statements of policy); *see generally* Perez v. Mortgage Bankers Ass'n, 575 U.S. 92, 96 (2015).

17. *See Allina*, 139 S. Ct. at 1811, 1814.

18. *See id.* at 1811.

19. Under the APA, the exception for interpretive rules gives the agency the authority to gap-fill and that authority results in the extension of judicial deference to agency decisions: "If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute. Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction

substantive require notice-and-comment rule making, if they are to be given legal effect; rules that are procedural, even though they may be ultimately determinative of an outcome, do not require notice-and-comment rule making.[20]

Allina has largely been treated by academics and commentators as a limited ruling on a niche issue of administrative procedure.[21] In actuality, however, by articulating the procedural requirements that must be met in order for CMS to impose a standard affecting payment as a rule with the "force and effect of law," (*i.e.*, by subjecting all substantive rules that govern payment for services to notice-and-comment), *Allina* has far-reaching implications for healthcare industry liability under the FCA. Most importantly, it limits those requirements that can be considered to be legally binding—and, therefore, can serve as a predicate for FCA liability—to those that are substantive and properly adopted via notice-and-comment rulemaking. All other guidance is sub-regulatory and has only some evidentiary utility in establishing scienter (as evidence that industry participants were aware of the rule) and that the government views a requirement as material (as opposed to defining the substance of the rule at issue).[22]

Allina, therefore, unceremoniously and without explicit recognition, sets a clear boundary between technical and immaterial violations of

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of a statutory provision for a reasonable interpretation made by the administrator of an agency." Chevron U.S.A. Inc. v. Natural Resources Defense Council, 467 U.S. 837, 843–44 (1984); *see also* Kisor v. Wilkie, 588 139 S. Ct. 2400, 2418 (2019) (discussing the latitude given to agencies to interpret their own regulations under the so-called *Auer* deference, and imposing no restrictions related to whether or not the interpretation infringes on a right or creates a new obligation, but rather looking only to whether there is a genuine ambiguity in the regulation, the agency's interpretation is reasonable, and the character and context of the agency interpretation entitles it to controlling weight and concluding that: "The upshot of all this goes something as follows. When it applies, Auer deference gives an agency significant leeway to say what its own rules mean. In so doing, the doctrine enables the agency to fill out the regulatory scheme Congress has placed under its supervision.").

20. *See* JARED P. COLE & TODD GARVEY, CONG. RESEARCH SERV., GENERAL POLICY STATEMENTS: LEGAL OVERVIEW 1 (2016), https://fas.org/sgp/crs/misc/R44468.pdf [https://perma.cc/R86Z-WPRB].

21. *See, e.g.*, Abbe R. Gluck & Anne Joseph O'Connell, *Opinion Analysis: Notice and Comment Under the Medicare Act, No Big Moves for the* APA, SCOTUSBLOG, (June 4, 2019, 10:54 AM), https://www.scotusblog.com/2019/06/opinion-analysis-notice-and-comment-under-the-medicare-act-no-big-moves-for-the-apa/ [https://perma.cc/TTM6-RSR7]; *see also* Allisa Newman, *A Lesson in Statutory Interpretation: Azar v. Allina Health Services and Implications for the Healthcare and Administrative Law Worlds*, MINN. L. REV.: BLOG (Feb. 27, 2019), https://minnesotalawreview.org/2019/02/27/a-lesson-in-statutory-interpretation/ [https://perma.cc/G879-3RD5].

22. *See generally Allina,* 139 S. Ct. at 1804.

CMS policy and the potential universe of violations of CMS rules sufficient to support an allegation of legal falsity under the FCA. Following *Allina,* the set of rules that can be considered material for purposes of an FCA action is restricted to substantive, binding rules.[23] Not all of these rules will be material, however, thereby further restricting the rules that can be used as a predicate for such liability. In other words, status as a properly promulgated substantive rule is necessary but not sufficient for FCA liability to follow.

In Section I below, for background and context, we turn to a discussion of the history and dynamics of the FCA. In particular, we focus on the parameters of a claim of legal falsity and explore examples of cases where deviations from sub-regulatory guidance have been used as a basis for asserting legal falsity under the FCA. This Section demonstrates that, notwithstanding the fact that the FCA is intended to address only material misrepresentations that constitute a fraud against the government, utilizing a theory of legal falsity, the government has bootstrapped non-binding, sub-regulatory guidance into legal effect via traditional deference analysis, thereby using the FCA as an all-purpose regulatory and sub-regulatory enforcement mechanism. In Section II below, we discuss the materiality standard articulated in *Escobar*, and in Section III, we demonstrate that this standard has proved too abstract and unpredictable a measure to curtail the use of the FCA in this overly-broad and punitive manner. In Section IV, we explore the meaning of the holding in *Allina* that establishes which CMS rules are binding. In Section V, we show how applying *Allina's* holding to screen out non-binding rules, significantly narrows the field of standards upon which the materiality test must be applied, ensuring that the materiality test will be applied only to rules that are significant enough that the government has seen fit to enact them by notice-and-comment rulemaking. While *Escobar's* materiality standard remains opaque, applying the holding of *Allina* to FCA legal falsity cases in the manner that we propose in Section VI will go a long way in providing much needed fairness and predictability to FCA enforcement and promoting appropriate use of the FCA, which carries harsh penalties to punish and deter fraud, and avoid use of the FCA as an all-purpose regulatory and contractual enforcement mechanism.

I. THE FEDERAL FALSE CLAIMS ACT

A. A Brief Background of the FCA

The FCA is a civil war-era statute designed to punish contractors who submit false claims to the government for payment for items or

23. *See id.* at 1805.

services.[24] It imposes liability on any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or] knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim."[25] Due to both the sheer volume of federal spending on healthcare and the complexity of the rules governing federal healthcare reimbursement, there are many opportunities to use the FCA to prosecute fraud in connection with federal health care programs.[26] Indeed, sixty-six percent of all FCA cases brought in 2018 dealt with claims submitted to the U.S. Department of Health and Human Services.[27] The FCA authorizes private citizens, known as "relators," to step into the shoes of the United States and to bring actions on the government's behalf, and incentivizes relators to do so by providing them with a share of the substantial damages and penalties available under the FCA.[28] FCA suits are, consequently, quite common, with whistleblowers, alone, filing 645 qui tam suits in fiscal year 2018, constituting eighty-four percent of all FCA suits filed that year.[29]

The Medicare Act has at its disposal a number of tools to assure that Medicare gets what it is paying for. These include suspension of

24. David L. Haron et al., *Bad Mules: A Primer on the Federal and Michigan False Claims Acts*, 88 MICH. BAR J. 22, 22 (2009).

25. 31 U.S.C. § 3729(a)(1)(A-B) (2018). Liability under the False Claims Act occurs when a person: (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; [or] (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

26. *See* Haron et al., *supra* note 24.

27. *See* Suzanne Jaffe Bloom, Benjamin Sokoly & Cristina I. Calvar, *False Claims Act, Government Fraud, & Qui Tam Litigation*, WINSTON & STRAWN LLP (Jan. 11, 2019), https://www.winston.com/print/content/1016897/false-claims-government-program-fraud-and-qui-tam-litigation.pdf [https://perma.cc/CFE2-43RK] ("Furthermore, fiscal year 2018 saw the commencement of 506 new FCA matters (nearly 66 percent of the 767 new matters initiated) involving the health care industry.").

28. *See* U.S. Dep't of Justice, *supra* note 2 (noting that the Department of Justice obtained more than $2.8 billion in settlements and judgments from civil cases involving fraud and false claims against the government in the fiscal year ending Sept. 30, 2018).

29. *Id.*

payment,[30] recoupment,[31] program exclusion,[32] civil money penalties,[33] recovery of damages,[34] criminal prosecution,[35] and corporate integrity agreements,[36] to name a few. Among this arsenal of tools to protect the integrity of federal healthcare spending, the FCA is favored because it allows for prosecution by private citizen relators and the possibility of collections not only of treble damages, but also substantial per-claim penalties.[37] Given that a finding of FCA liability requires that the defendant have engaged in a fraud and applies penalties without reference to real economic damage, the FCA is not, however, always an appropriate tool for mediating payment disputes. Payment disputes are, fundamentally, contractual disputes. What is more, they may arise from differing or insignificant interpretations of payment-related guidance or rules, and in situations where the government has received most, if not all, of what it has paid for.

B. Factual Falsity

In its most straightforward form, the FCA bars "factually false" claims to the federal government for reimbursement for items or services that have not been provided (*e.g.*, delivering 10 mules and billing for 100 racehorses).[38] A claim may also be factually false if it is for items or serviced provided in a manner that deviates from what is claimed to have been provided (*e.g.*, billing for transporting 100 racehorses in time for Monday's race, and delivering the horses on Tuesday).[39] In both instances, the claims for reimbursement would be "factually false" because the claimant misrepresented a fact about the item or service for which the government has paid. With respect to Medicare, both claims for a health care item or service that was not provided, and claims for items or services that were provided, but in a manner that

30. *E.g.,* 42 U.S.C. § 1395mm (2018).

31. *E.g.,* 42 C.F.R. § 405.371 (2019).

32. *E.g.,* 42 U.S.C. § 1320a-7 (2018).

33. *E.g.,* 42 U.S.C. § 1395i-3 (2018).

34. *E.g.,* 31 U.S.C. § 3729 (2018).

35. *E.g.,* 42 U.S.C. § 1395ss (2018).

36. *See* 42 U.S.C. § 1395ddd (2018).

37. *See* 31 U.S.C. §§ 3729(a), 3730 (2018).

38. *See* Mikes v. Straus, 274 F.3d 687, 697 (2d Cir. 2001). "False claims" under the FCA take a variety of forms. In the paradigmatic case, a claim is false because it "involves an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Id.*

39. *See, e.g.*, United States v. Kellogg Brown & Root Servs., Inc., 800 F. Supp. 2d 143, 154 (D.D.C. 2011) (citing United States v. Sci. Applications Int'l Corp. (SAIC II), 626 F.3d 1257, 1266 (D.C. Cir. 2010)).

was "so insufficient and negligent that the claims . . . amounted to fraud," could be factually false.[40] As one commentator explained: "Substandard care may be so extreme as to lead to factually false claims, or claims for worthless services."[41]

In a recent example of a criminal FCA case predicated on a theory of factual falsity, the government alleged that a defendant submitted a claim for reimbursement for services that were not provided. In that case, the U.S. Attorney for the Southern District of New York indicted an ophthalmologist for healthcare fraud, alleging that the physician ("GOYAL") fraudulently billed millions of dollars "for complex eye surgeries that GOYAL had not actually performed . . . . GOYAL and his Practice engaged in widespread healthcare fraud by consistently 'upcoding' these and other surgical procedures, examinations, and tests in fraudulent billings submitted to Medicare and Medicaid . . . . GOYAL also falsified patient medical records, pressured other employees in his Practice to engage in the scheme, and initiated debt collection proceedings against patients who did not pay the full amounts of his fraudulently billed charges."[42]

Another recent FCA case in the Ninth Circuit that was predicated on a theory of factual falsity involved allegations that a service was so worthless that to bill for it amounted to a false claim.[43] In this case, allegations included that the operator of regional clinical laboratories had falsified laboratory test data when test results fell outside the acceptable standard of error, rendering useless tests that were billed to Medicare as performed.[44] The court explained: "[i]n an appropriate case, knowingly billing for worthless services or recklessly doing so with deliberate ignorance may be actionable under § 3729 [of the False Claims Act], regardless of any false certification conduct."[45] Commenting on this holding, the Second Circuit stated: "We agree that a worthless services claim is a distinct claim under the Act. It is

40. *See* United States v. NHC Health Care Corp., 163 F. Supp. 2d 1051, 1053 (W.D. Mo. 2001).

41. John T. Brennan, Jr. & Michael W. Paddock, *Limitations on the Use of the False Claims Act to Enforce Quality of Care Standards*, J. HEALTH & LIFE SCI. LAW 39, 48 (2008), https://www.crowell.com/documents/Use-of-the-False-Claims-Act-to-Enforce-Quality-of-Care-Standards.pdf [https://perma.cc/CN5H-5ECU].

42. Press Release, U.S. Attorney's Office, S. Dist. of N.Y., Manhattan U.S. Attorney Announces Indictment and Arrest of Ophthalmologist for Healthcare Fraud (Nov. 22, 2019), https://www.justice.gov/usao-sdny/pr/manhattan-us-attorney-announces-indictment-and-arrest-ophthalmologist-healthcare-fraud [https://perma.cc/JSD4-ZSAB].

43. United States *ex rel.* Lee v. SmithKline Beecham, Inc., 245 F.3d 1048, 1050 (9th Cir. 2001).

44. *Id.*

45. *Id.* at 1053.

effectively derivative of an allegation that a claim is factually false because it seeks reimbursement for a service not provided. In a worthless services claim, the performance of the service is so deficient that for all practical purposes it is the equivalent of no performance at all."[46]

The theory of these cases is that the claim that was submitted to the government for payment overtly misrepresented what was provided, and was, therefore, fraudulent. These cases are not predicated on any non-compliance with the underlying law, although sometimes deficiencies that relate to the quality of services can also be attacked under theories of legal falsity.[47]

C. Legal Falsity as Grounds for FCA Liability

Liability under the FCA may also be predicated on a theory that claims for reimbursement may be "legally false."[48] Although the FCA is "not designed to reach every kind of fraud practiced on the Government,"[49] it was intended to address at least some subset of claims that are deficient due to failure to comply with laws governing reimbursement. Thus, "a false claim may take many forms, the most common being a claim for goods or services not provided, or provided

46. Mikes v. Straus, 274 F.3d 687, 703 (2d Cir. 2001) (citations omitted).

47. In *Mikes,* for example, the relator (Mikes) alleged that the defendant medical practice had performed a diagnostic spirometry test in a sub-standard manner. Mikes claimed that medical society guidelines set out the generally accepted standards for spirometry. To ensure accuracy, these guidelines recommend daily calibration of spirometers and performance of multiple trials during test administration, as well as the appropriate training of spirometer technicians. *Id.* at 694. Mikes maintained "that defendants' performance of spirometry did not conform to the . . . guidelines and thus would yield inherently unreliable data. She argue[d] that defendants allowed medical assistants to perform spirometry tests when they were not trained in its proper administration. . . . The thrust of plaintiff's *qui tam* suit is that the submission of Medicare reimbursement claims for spirometry procedures not performed in accordance with the relevant standard of care, that is, the . . . Guidelines—violates the False Claims Act" because the tests were not medically necessary, as required by the Act. *Id.* at 694, 696.

48. *See id.* at 696–97. Here, the government's case relies on the so-called "certification theory" of liability, or alternatively "legally false certification." *See id.* at 696–97. Under this theory, a claim for payment is false when it rests on a false representation of compliance with an applicable federal statute, federal regulation, or contractual term. *Id.* at 696. False certifications can be either express or implied. *Id.* at 698–99. Courts infer implied certifications from silence "where certification was a prerequisite to the government action sought." United States ex. rel. Siewick v. Jamieson Sci. & Eng'g, Inc., 214 F.3d 1372, 1376 (D.C. Cir. 2000).

49. United States v. McNinch, 356 U.S. 595, 599 (1958).

in violation of contract terms, specification, statute, or regulation."[50] This latter category of false claim—claims provided in violation of contract terms, specification, statute, or regulation—are considered to be "legally false" under the theory that the government would not have paid the claim had the government been apprised of the alleged legal non-compliance. A claim is legally false, therefore, when the claimant has falsely certified, either impliedly or explicitly, that, in the process of delivering the item or service for which reimbursement is claimed, she complied with a statute or regulation that is a "material condition of payment."[51]

In the absence of an express false certification that attests to compliance with a particular law, as may be made in connection with a provider agreement or other signed document submitted to the government, the concept of legal falsity under the FCA relies on an implied false certification theory of liability.[52] The implied false certification theory of liability posits that, by submitting a claim, a claimant impliedly certifies compliance with all of the reimbursing program's conditions of payment.[53] If in doing so, the claimant fails to disclose non-compliance with a violation of a statutory, regulatory, or contractual requirement which, had the claimant disclosed it, would have caused the government not to pay the claim, the claimant has made a misrepresentation that is false for purposes of the FCA.

Carrying harsh (and sometimes ruinous) financial penalties, the FCA is designed to punish fraud, not to compensate for mere breach of contract.[54] The core analytical problem for implied false certification

50. S. REP. NO. 99-345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274.

51. Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 1993 (2016).

52. *See, e.g.,* United States *ex rel.* Hendow v. Univ. of Phoenix, 461 F. 3d 1166, 1172 fn. 1 (2006) ("Some courts . . . have adopted a version of the false certification theory whereby the certification need only be implied, rather than express. In those cases, if a party submits a claim for payment under a government program with requirements for participation, that claim is taken as an implied certification that the party was in compliance with those program requirements. *See Ab-Tech Constr., Inc. v. United States*, 31 Fed.Cl. 429, 434 (Fed.Cl.1994). Here, we need not address the viability of this theory, because it is beyond dispute that the University signed the written Program Participation Agreement, thus making an express statement of compliance.").

53. *Id.*

54. The FCA provides for "a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104–410 [1]), plus 3 times the amount of damages which the government sustains because of the act of that person." 31 U.S.C. § 3729(a)(G) (2018). *See also* Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens, 529 U.S. 765, 784–85

claims has always been how to define exactly the universe of laws with which non-compliance could render a claim fraudulent. With respect to Medicare, legally false claims are often predicated on non-compliance with a key federal anti-abuse statute, such as the Anti-kickback Statute ("AKS")[55] or the Physician Self-Referral Law (the "Stark Law").[56] Beyond non-compliance with clearly binding law, however, many FCA cases assert non-compliance with one of the myriad of sub-regulatory standards relating to how Medicare items and services are to be provided, documented, or billed without much consideration as to whether such standard is expressed in NCDs, local coverage decisions ("LCDs"), program manuals, training presentations, website postings, courses of dealing, or other sub-regulatory guidance.[57]

There are numerous examples of FCA legal falsity cases alleging non-compliance not with the law, but, rather, with sub-regulatory interpretations of the law. While some of these cases evidence a concern that attaching such harsh penalties to sub-regulatory requirements may be cause for pause, they tend to gloss over the issue. For example, one typical case considered whether an FCA claim could be predicated on non-conformance in the performance of radiology services with standards expressed in an LCD. The court, while allowing for some doubt as to the significance of sub-regulatory guidance,[58] concluded that

(2000) (noting that damages under the FCA are "essentially punitive in nature," and that the FCA's treble damages provision "reveals an intent to punish past, and to deter future, unlawful conduct, not to ameliorate the liability of wrongdoers").

55. *See* 42 U.S.C. § 1320a-7b(b) (2018).

56. *See* 42 U.S.C. § 1395nn (2018).

57. *See, e.g.*, Shalala v. Guernsey Memorial Hosp., 514 U.S. 87, 101 (1995) (designating a Medicare Manual provision as an interpretive rule.); Christensen v. Harris County, 529 U.S. 576, 587 (2000) (while it is true that rules found in manual such as the PRM are entitled to less deference than interpretations arrived at after a formal adjudication or notice-and-comment rulemaking, this does not mean that the rules in the Manual are entitled to any deference at all. If an interpretive rule is neither inconsistent with promulgated regulations, nor outside the coverage of the Act, it is valid).

58. United States v. Space Coast Med. Associates, L.L.P., 94 F.Supp.3d 1250, 1260 n.13 (2015) ("As for whether LCDs are rules that, upon their violation, can result in liability under the False Claims Act, some courts analyze alleged violations of LCDs as possible violations of the False Claims Act . . . Because these documents detail the requirements for payment and billing for particular procedures and are statutorily defined as determining coverage, 42 U.S.C. § 1395ff(f)(2)(B), the Court will consider them as potential bases for liability in this case."); *see also* Hericks v. Lincare Inc., No. 07-387, 2014 WL 1225660, at *10–11 (E.D. Pa. Mar. 25, 2014) (holding that the applicable LCD did not address the type of conduct at issue). Other courts, however, note that LCDs are issued by contractors and express doubt that requirements found in these

if an LCD or Manual provision focuses on procedures and codes for billing for the services, non-conformance with LCD or Manual provision could form a basis for a claim alleging legal falsity, reasoning, somewhat tautologically, that:

> [I]n addition to statutes and regulations, LCDs—issued by private local entities contracting with the government set forth and govern the conditions of coverage and reimbursement under Medicare . . . .
>
> Relators allege that Defendants delivered radiation treatment [in a manner that] violated an LCD [that required certain documentation that was] signed by both the radiation oncologist and the medical physicist . . . Because this LCD focuses on procedures and codes for billing for the services, the Court finds that this documentation is a condition of payment for Medicare . . . .
>
> Relators also allege that Defendants violated an LCD by delivering radiation treatment prior to or without performing quality assurance evaluations . . . . As with [the other LCD, this LCD's] requirements focus on billing and coding, so a violation of the determination could be an implied false certification of a payment condition.[59]

In a very recent settlement, a genetic testing company, GenomeDx Biosciences Corp. ("GenomeDx") agreed to pay $1.99 million to resolve allegations that it violated the FCA by submitting claims to Medicare for genetic tests for prostate cancer patients in violation of LCD requirements.[60] The claimed services were fully rendered as billed, but

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determinations can serve as a basis for an FCA violation, especially where the relators did "not cite to a statute or regulation that conditions payment of a Medicare claim on compliance with any LCD." United States *ex rel.* McMullen v. Ascension Health, No. 3-12-0501, 2013 WL 6073549, at *2 n.3 (M.D. Tenn. Nov. 18, 2013).

59. 94 F.Supp.3d 1250, at 1260–62. *But cf.* United States *ex rel.* McMullen v. Ascension Health, No. 3-12-0501, 2013 WL 6073549, at *2 n. 3 (M.D. Tenn. Nov. 18, 2013) ("Relator contends that these alleged requirements were found in certain 'LCDs' . . . . Relator admits, however that the LCDs were issued by contractors, not by the government. Defendants argue that the LCDs are merely guidance, not published regulations. Whether the LCDs applied to Defendants is a contested factual issue, but Relator does not cite to a statute or regulation that conditions payment of a Medicare claim on compliance with any LCD.") (citation omitted). *See generally* Chesbrough v. VPA, P.C., 655 F.3d 461 (6th Cir. 2011) (dismissing the Relator's claims because they were not grounded in a Federal statute or regulation).

60. Press Release, U.S. Dep't of Justice, Genetic Testing Company Agrees to Pay $1.99 Million to Resolve Allegations of False Claims to Medicare for

allegedly failed to meet nuanced requirements that patients must show certain "risk factors" before the tests could be billed.[61] These "risk factor" requirements were articulated not by statute or by regulation, nor were they articulated by CMS in sub-regulatory guidance. Instead, the requirements were found in an LCD.[62]

These cases demonstrate how defendants have faced the risk of substantial FCA liability for failure to comply with requirements articulated in CMS sub-regulatory guidance or, as in the GenomeDX case, as well as the two OIG Reports, guidance issued by third-party contractors who administer aspects of federal healthcare programs. Such cases show the long reach that the theory of legal falsity bestows on the FCA, allowing a remarkably wide range of non-compliance with programmatic rules to potentially serve as a predicate for FCA liability.[63]

Medically Unnecessary Tests (Feb. 11, 2019), https://www.justice.gov/opa/pr/genetic-testing-company-agrees-pay-199-million-resolve-allegations-false-claims-medicare [https://perma.cc/JLE3-6534].

61. *Id.*

62. Complaint and Demand for Jury Trial at 2, United States *ex rel.* La Fleur v. GenomeDX Biosciences Corp., No. 3:17-cv-01959 (S.D. Cal. 2017), https://www.docketbird.com/court-documents/La-Fleur-et-al-v-GenomeDX-Biosciences-Corp/COMPLAINT-with-Jury-Demand-against-GenomeDX-Biosciences-Corp-Filing-Fee-400-Receipt-Number-CAS094697-filed-by-Stephanie-La-Fleur-Corinne-Vause/casd-3:2017-cv-01959-00001 [https://perma.cc/Y8FJ-RKYR]. The LCD at issue required that patients have risk factors such as "pathological stage T2 disease with a positive surgical margin, pathological stage T3 disease or rising Prostate-Specific Antigen (PSA") levels after an initial PSA nadir." *See* U.S. Dep't of Justice, *supra* note 60. In fact, the complaint in this case alleges a much more complex and problematic set of facts involving active misrepresentation of the test conducted as something other than it was. *See* Complaint & Demand for Jury Trial, United States v. GenomeDx Biosciences Corp., No. 3:17-cv-01959-L-WVG (S.D. Cal. Sept. 26, 2017). Also, in the two OIG Reports discussed below in Section II.C.iii, the OIG seems to conclude that non-conformance with sub-regulatory documentation requirements renders a payment an over-payment, such that retention of the payment after notice of non-compliance would constitute a "reverse" false-claim.

63. Outside of the FCA sphere, applying traditional APA deference analysis, courts have typically granted HHS broad latitude in what it may require from providers as a precondition to payment, beyond that which is stipulated in statute or regulations. *See, e.g.,* Maximum Comfort Inc. v. Sec'y of Health & Hum. Servs., 512 F.3d 1081, 1083 (9th Cir. 2007). A typical approach is to employ the "two-step approach of *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc* . . . [under which we] first ask whether the Medicare Act speaks directly to the question presented. 'If the intent of Congress is clear, that is the end of the matter,' and this Court must give effect to Congress's expressed intent. If, on the other hand, the Medicare Act is silent or ambiguous with respect to the question presented, then this Court asks 'whether the [Secretary's] answer

II. *UNIVERSAL HEALTH CARE SERVICES, INC. V. UNITED STATES EX REL. ESCOBAR*

As recently as 2016, circuit courts disagreed as to whether, and to what extent, the FCA countenanced legally false claims.[64] In its seminal opinion in *Universal Health Services v. United States ex rel. Escobar*, however, the U.S. Supreme Court confirmed that FCA cases could be brought under a false certification theory, putting to bed the long-standing question of whether a claim could be false for the purposes of the FCA even if the claim did not factually misrepresent what was being billed to the government.[65] The relators in *Escobar*—parents of a teenager who died while under the care of Defendant Universal Health (a mental health provider) alleged that Universal Health defrauded the government by submitting claims for reimbursement to Medicaid for professional services performed by individuals who were not properly licensed to perform the services under Massachusetts law.[66] The Court held that a claim may be legally false by reason of a violation of regulations governing the services because, in submitting the claim, the provider had impliedly certified that the services met CMS's requirements of conformance with those regulations.[67] The Court thus resolved a longstanding inter-circuit conflict over validity of the implied false certification theory of liability under which a claim may be held to be legally false for purposes of FCA liability.[68]

Building on a number of cases that sought to distinguish mere breaches of contract from non-conformance that amounted to a fraud,[69]

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is based on a permissible construction of the statute.'" *Id.* at 1086 (citation omitted). If the statute is "silent or ambiguous with regard to the Secretary's power to require additional information . . . . the interpretation of the Secretary is certainly reasonable and entitled to deference under *Chevron*." *Id.* at 1088 (citation omitted). Under this approach, once the requirements are accorded judicial deference, they serve to dispositively elucidate the underlying statutory and regulatory requirements, thereby requiring, in effect, compliance with the position expressed in the guidance.

64. *See, e.g.*, Universal Health Servs., Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989 (2016) (and cases cited therein).

65. *Id.* at 1995, 1999.

66. *Id.* at 1993.

67. *Id.* at 1993–94.

68. *Id.* at 1998–99.

69. *See, e.g.*, United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1270–71 (D.C. Cir. 2010) ("As [the defendant] SAIC compellingly points out, without clear limits and careful application, the implied certification theory is prone to abuse by the government and *qui tam* relators who, seeking to take advantage of the FCA's generous remedial scheme, may attempt to turn the violation of minor contractual provisions into an FCA

the *Escobar* Court noted that a violation of any regulatory requirement would not necessarily render a claim legally false.[70] Indeed, even a violation of a regulation labeled a "condition of payment" or a "condition of participation" in the regulatory text would not necessarily render a claim false.[71] Rather, whether violation of a regulatory requirement renders a claim false under an implied false certification theory of liability turns on whether, in practice, the agency treated the requirement as material to payment.[72] In other words, the relevant question under *Escobar* is whether the agency would have actually paid the claim had the agency realized that the regulatory requirement had not been met.[73] *Escobar's* holding means that every FCA case predicated on a theory of legal falsity necessitates an inquiry into whether or not the particular condition at issue was considered by the government to be material to payment.

The *Escobar* Court, notably, did not place any boundaries on the universe of requirements that could potentially be considered material. The Court provides only hints as to how materiality may be established, relying instead on a fact-specific assessment of the particular case.[74] Thus, the Court left the essential question of all legal falsity claims—exactly when a violation of law renders an otherwise truthful claim false—to be determined by lower courts with only vague guidance that courts should look for evidence that the law at issue was "material" to the federal government's decision to pay the claim.

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action. In our view, however, instead of adopting a circumscribed view of what it means for a claim to be false or fraudulent, this very real concern can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements . . . . To establish FCA liability under an implied certification theory, the plaintiff must prove by a preponderance of the evidence that compliance with the legal requirement in question is material to the government's decision to pay. By enforcing this requirement rigorously, courts will ensure that government contractors will not face 'onerous and unforeseen FCA liability' as the result of noncompliance with any of 'potentially hundreds of legal requirements' established by contract. Payment requests by a contractor who has violated minor contractual provisions that are merely ancillary to the parties' bargain are neither false nor fraudulent.") (internal citations omitted).

70. *See e.g.* Universal Health Servs. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 1996 (2016).

71. *Id.*

72. *See id.*

73. *See id.* The *Escobar* Court held that the label the government attaches to a requirement is relevant but not dispositive to a determination of materiality and the defendant's knowledge of materiality. *Id* at 1995, 2001.

74. *Id.* at 2001–04.

A. Escobar's Open-Ended Materiality Standard and the Unbounded Universe of CMS Rules and Regulations

In determining how best to approach an implied false certification theory of FCA liability, The *Escobar* Court catalogued the approaches taken by circuit courts: (1) the Seventh Circuit rejected the theory because only express (or affirmative) falsehoods can render a claim "false or fraudulent" under the FCA; (2) other courts have accepted the theory only as to failures to disclose violations of expressly-designated "conditions of payment;" and (3) other courts held that a claim could be legally false by virtue of non-compliance with an undefined subset of regulations that were, in practice, conditions of payment, though they may or may not be expressly designated as such.[75] The Supreme Court followed the last approach, holding that "liability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but knowingly fails to disclose the defendant's noncompliance with a statutory, regulatory, or contractual requirement. In these circumstances, liability may attach if the omission renders those representations misleading."[76]

In keeping with the FCA's statutory requirement of materiality and incorporating common law doctrine on the topic, the *Escobar* Court held that, in order to be actionable under the FCA, the omission must not only be misleading, but material:

> What matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the government's payment decision . . . . A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the government's payment decision in order to be actionable under the False Claims Act. We clarify below how that rigorous materiality requirement should be enforced.[77]

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75. *Escobar*, 136 S. Ct. at 1998–99. "If the government contracts for health services and adds a requirement that contractors buy American-made staplers, anyone who submits a claim for those services but fails to disclose its use of foreign staplers violates the False Claims Act . . . . Likewise, if the government required contractors to aver their compliance with the entire U. S. Code and Code of Federal Regulations, then under this view, failing to mention noncompliance with any of those requirements would always be material. The False Claims Act does not adopt such an extraordinarily expansive view of liability." *Id.* at 2004. 31 U.S.C. § 3729(b)(4) (2018).

76. *Escobar*, 136 S. Ct. at 1995.

77. *Id.* at 1996.

Escobar, therefore, rejects the view "that any statutory, regulatory, or contractual violation is material so long as the defendant knows that the government would be entitled to refuse payment were it aware of the violation."[78] Rather, *Escobar* made evidence of actual materiality a key gatekeeper to FCA liability.[79] Without the requirement of materiality, knowing non-conformance with any of the myriad statutory, regulatory, and contractual requirements imposed by federal health care programs would give rise to FCA liability.[80]

Nevertheless, the Court did not articulate an objective test for materiality, but instead recommended a fact-based, case-by-case approach to determining materiality. The Court explained that any evidence of how the government treats a requirement, in practice, is relevant to a determination of materiality:

> [T]he term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property . . . . The materiality standard is demanding. The False Claims Act is not "an all-purpose antifraud statute," or a vehicle for punishing garden-variety breaches of contract or regulatory violations. A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial . . . . [P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement. Conversely, if the government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material. Or, if the Government regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material.[81]

78. *Id.* at 2004.

79. *Id.* at 2001–02.

80. *Id.* at 2003.

81. *Id.* at 2002–04 (internal citations omitted). In a footnote, the Court states: "We reject Universal Health's assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment. The standard for materiality that we have outlined is a familiar and rigorous one." *Id.* at 2004, n.6.

Under this approach, materiality is not to be judged solely by reference to what the government says is material, but rather by what the government treats as material in practice. While this limitation is important to keep FCA liability from extending to such clearly-ancillary requirements, as the Court put it, that all healthcare providers "buy American-made staplers,"[82] it also places healthcare providers in the precarious position of being unable to conclusively rely on the government's explicit designation of a standard as material, or to conclude that in the absence of such a designation, a standard is immaterial. While the Court considered the risk of predictability posed by such a contextual materiality standard, as discussed in detail herein, the Court assumed that the FCA's scienter requirement would do the work of limiting the set of requirements to which FCA liability may attach.[83] The Court acknowledged that the defendant's knowledge of the government's view that a standard is material is critical and cannot be assumed.[84]

82. *Id.* at 2004.

83. *Id.* at 2002.

84. *Id.* at 2003–04. Of course, evidence of materiality (e.g., historical non-payment or government statements) will often serve as evidence of knowledge. Even cases alleging violations of significant anti-fraud statutes, such as Stark or the AKS as the source of legal falsity, must also address the question of whether or not the deviation is material. One court concluded that there had been a violation of Stark because the parties had failed to comply with a requirement in Stark that certain arrangements be memorialized in writing, and then turned to considering whether the violation was material for purposes of the FCA; it held:

> Applying the *Escobar* factors to the instant case, it is clear that the alleged violations at issue here are material. As an initial matter, the Stark Act expressly prohibits Medicare from paying claims that do not satisfy each of its requirements, including every element of any applicable exception. The relevant exceptions expressly require that any financial arrangements that would otherwise violate the Stark Act must be set forth in writing. Although "statutory, regulatory, and contractual requirements are not automatically material, even if they are labeled conditions of payment," they nevertheless represent "relevant" evidence in favor of materiality.
>
> Compliance with the writing requirement permits a reviewer to analyze the timeframe, rate of compensation, and the identifiable services contemplated in the arrangement to determine whether any portion is based on the volume or value of physician referrals. CMS guidance also requires a signature as a manifestation of the parties' assent to the arrangement, a requirement that "plays a role in preventing fraud and abuse." These requirements go to the very "essence of the bargain" between the government and health care providers with respect to Stark Act compliance.

In the wake of *Escobar*, the newly-articulated materiality requirement was widely viewed as providing a workable limitation on the scope of FCA liability.[85] The court in *Ruckh v. CMC II LLC et al.* described *Escobar* as: "reject[ing] a system of government traps, zaps, and zingers that permits the government to retain the benefit of a substantially conforming good or service but to recover the price entirely—multiplied by three—because of some immaterial contractual or regulatory non-compliance."[86] The *Ruckh* court noted that the FCA, instead, "requires proof that a vendor committed some non-compliance that resulted in a material deviation in the value received and requires proof that the deviation would materially and adversely affect the buyer's willingness to pay."[87] In practice, however, divining the government's mindset *vis a vis* payment has involved a fair amount of speculation, causing the post-*Escobar* experience with respect to federal healthcare reimbursement to fail to meet expectations of increased consistency, predictability, and simplicity.[88] Fundamentally, an approach to assessing legal falsity that does not provide any clear limitations on the universe of programmatic requirements that could form the basis of an FCA suit does not properly account for the fact that "Medicare is a massive federal program, 'embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations.' . . . [T]he agency has issued tens of thousands of pages of Manual instructions, interpretive rules, and other guidance

> On balance, a reasonable jury could find that the materiality requirement of the FCA is satisfied in the instant case. The writing requirements contained in several Stark Act exceptions are important, mandatory, and material to the government's payment decisions.

United States *ex rel.* Emanuele v. Medicor Ass'n, 242 F. Supp.3d 409, 431–32 (W.D. Pa. 2017) (internal citations omitted).

85. United States *ex rel.* Ruckh v. Salus Rehab, L.L.C., 304 F. Supp. 3d 1258, 1268 (M.D. Fla. 2018); Skadden, Arps, Slate, Meagher & Flom LLP & Affiliates, *Escobar and the Implied Certification Theory: Initial Cases Raise the Bar on Materiality in False Claims Act Litigation,* SKADDEN (Nov. 7, 2016), www.skadden.com/insights/publiactions/2016/11/emescobarem-and-the-implied-certification-theory-i [https://perma.cc/R7X4-SMWV]; G. Christian Roux & John D. Hanover, *Implied False Certification Liability Under the False Claims Act: How the Materiality Standard Offers Protection After Escobar*, 38 CONSTRUCTION LAW. 16, 21 (2018); *but cf.*, C. Joel Van Over et al., *Client Alert: Supreme Court Validates 'Implied Certification' Liability under False Claims Act,* PILLSBURYLAW (June 23, 2016), www.pillsburylaw.com/images/content/1/0/v2/106294/AlertJune2016GovConSupremeCourtValidatesImpliedCertificationLiab.pdf [https://perma.cc/KN7B-EMGG].

86. *Ruckh*, 304 F. Supp. 3d at 1263.

87. *Id.*

88. *See infra* Section II.C.

documents."[89] In articulating a standard that hinges on highly contextual and individualized assessments of programmatic rules, the Supreme Court failed, moreover, to recognize the fundamental nature of the health care industry, which operates on a system of adherence to tacit industry standards, not all of which have legal import.

The *Escobar* Court, consequently (and potentially inadvertently) made it possible that non-compliance with an indefinite universe of requirements, ranging from esoteric and technical billing instructions to qualitative standards of professional conduct, could render a claim fraudulent. Indeed, FCA cases have gone beyond use of sub-regulatory guidance as evidence of materiality, allowing requirements contained in sub-regulatory guidance to be treated as potentially material to payment in and of themselves.[90] After all, the *Escobar* Court construed only the question of non-conformance with a properly-adopted regulation. *Escobar* has left, in its wake, a glut of inconsistent case law that attempts to divine whether CMS would or would not have paid a claim had it known that a given requirement had not been met. This lack of consistency has left whistleblowers, prosecutors, and health care providers, alike, to guess as to where the line exists between a technical foot fault and a fraudulent claim.[91]

C. Scienter as a Failed Check on the Limitations of Escobar's Materiality Standard

While the *Escobar* Court entertained the possibility that its open-ended approach to analyzing legal falsity could sweep too broadly, the Court ultimately dismissed it, stating that the FCA's scienter requirement would reduce the risks posed by the unpredictability of a subjective materiality standard:

> [O]ther parts of the False Claims Act allay Universal Health's concerns [that the standard was too broad]. "[I]nstead of adopting a circumscribed view of what it means for a claim to be false or fraudulent," concerns about fair notice and open-ended liability

89. *Allina*, 139 S. Ct. at 1821–22 (2019) (Breyer, J., dissenting).

90. *See, e.g.*, *supra* notes 46–53 and accompanying text; United States *ex rel.* Prather v. Brookdale Senior Living Communities, Inc., 838 F.3d 750, 773–74 (6th Cir. 2016).

91. This ambiguity is only exacerbated in an enforcement scheme that relies almost exclusively on whistleblowers who may be inspired by opportunism, overly vigilant, or simply lacking in regulatory insights, so that prosecutorial discretion is not a regulating feature. The Medicare regulatory scheme is, moreover, so complex that courts are ill-equipped to navigate and understand Medicare requirements and to serve as effective gatekeepers for FCA claims, making it difficult for whistleblowers and defendants alike to predict where a court may land.

> "can be effectively addressed through strict enforcement of the Act's materiality and scienter requirements."[92]

The Court, therefore, anticipated that the scienter and materiality requirements of the FCA would serve as dual gates to FCA liability by separating inconsequential deviations from law from fraudulent deviations from law.

The requirement of scienter means that, in order to succeed on a claim under the FCA, a relator must show that the defendant acted "knowingly," which the FCA defines as either "actual knowledge," "deliberate ignorance," or "reckless disregard."[93] "The False Claims Act does not create liability merely for a health care provider's disregard of government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the government to pay amounts it does not owe. Accordingly, the fact that there may have been a violation of the laws governing Medicare . . . is not enough, standing alone, to sustain a cause of action under the False Claims Act."[94] In FCA claims alleging legal falsity, this means that the relator must show that the defendant *knew*: 1) that she had not met the legal requirement at issue, *and* 2) that the government would not have paid the claim had the government known that the requirement was not met.[95] With respect to the scienter requirement carried by the FCA, "Congress did not intend to turn the False Claims Act, a law designed to punish and deter fraud, into a vehicle either punishing honest mistakes or incorrect claims submitted through mere negligence or imposing a burdensome obligation on government contractors rather than a limited duty to inquire."[96]

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92. Universal Health Servs. Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 2002 (internal citations omitted).

93. 31 U.S.C. § 3729(b) (2018). "Specific intent to defraud is not required; however, liability does not attach to innocent mistakes or simple negligence." *Id.* § 3729(b).

94. United States *ex rel.* Phalp v. Lincare Holdings, Inc., 857 F.3d 1148, 1154–56 (11th Cir. 2017) (citations omitted).

95. *See, e.g.*, United States *ex rel.* Purcell v. MWI Corp., 807 F.3d 281 (D.C. Cir. 2015), *cert. denied*, 137 S. Ct. 625 (2017). The False Claims Act prohibits the knowing presentation of false claims for government payment or approval. *Id.* at 287. The Act defines "knowing" and "knowingly" to mean that the actor had actual knowledge of the pertinent information and acted in deliberate ignorance or in reckless disregard of the truth or falsity of that information. *Id.* The question on intent here is whether the defendants knew (or would have known absent deliberate blindness or reckless disregard) that their bills would lead the government to believe that they had provided services that they actually did not provide. *Id.* at 290. *See also* Minnesota Ass'n of Nurse Anesthetists v. Allina, 276 F.3d 1032 (8th Cir. 2002); United States v. Peter Mackby, 261 F.3d 821 (9th Cir. 2001).

96. *Phalp*, 857 F.3d at 1155.

While the *Escobar* Court envisioned that scienter would serve a key role in separating appropriate from overzealous FCA suits, post-*Escobar,* lower courts have struggled to apply this screen effectively and consistently.[97] One of the most confounding factors in legal falsity cases is that they are often predicated on assertions that the defendant has deviated from standards that are inherently ambiguous both as to meaning and as to whether or not the government considers them to be material.[98] Evaluating scienter in the face of ambiguous standards with uncertain import is challenging and has led to disparate approaches and results.

The Eleventh Circuit, for example, rejected the argument that ambiguity in meaning categorically precludes a finding that defendants acted "knowingly" as a matter of law.[99] It held that: "Although ambiguity may be relevant to the scienter analysis, it does not foreclose a finding of scienter. Instead, a court must determine whether the defendant actually knew or should have known that its conduct violated a regulation in light of any ambiguity at the time of the alleged violation."[100] However, the Eleventh Circuit did not elucidate the standards used to evaluate the degree of tolerable ambiguity in meaning, nor the evidence that would be relevant to such an inquiry, and the problem in identifying these standards seems even more difficult if one extends the analysis to the question of knowledge of materiality, which, as we have noted, will often be extremely unclear.

The Eighth Circuit has considered what this evidence might look like, ultimately holding that none of the evidence produced by the relator in the case at hand, nor the existence of an evident ambiguity in the standard alleged to have been violated, meant that the defendants knew that they were submitting false claims.[101] The court held that in answering the question of whether a FCA defendant's "reasonable interpretation of the ambiguous regulation precludes a finding that it knowingly submitted false or fraudulent claims" "evidence of government guidance that warned a regulated defendant away from an otherwise reasonable interpretation of an ambiguous regulation. . . . (such as) a Medicare agency memorandum (that) made it clear that anesthesiologists were not to leave a patient during a personally performed procedure" could support a finding of scienter.[102]

97. *See infra* Section II.C.

98. *Id.*

99. *Id.*

100. *Id.*

101. United States *ex rel.* Donegan v. Anesthesia Ass'n. of Kansas City, PC, 833 F.3d 874, 875 (8th Cir. 2016); *see also* United States *ex rel.* Hixson v. Health Mgmt. Sys., Inc., 613 F.3d 1186, 1190 (8th Cir. 2010).

102. *Donegan*, 833 F.3d at 879–80.

However, the court held that a report prepared "by a former Section Chief of CMS's predecessor . . . nearly two decades ago by a former agency official in another case is not the kind of official government warning that would be sufficient evidence of reckless disregard".[103] Further, the court held that the defendant did not have a duty to ask CMS or its local contractors whether its interpretation of the ambiguous terminology was proper, as "the agency had not clarified an obvious ambiguity in its . . . regulation for decades, (the defendant's) . . . 'failure to obtain a legal opinion or prior [CMS] approval cannot support a finding of recklessness.'" [104]

Underscoring the difficulty of relying on whether or not the defendant has been "warned away" from a particular interpretation as a definitive standard, another court held that in the face of ambiguity, a credible alternative interpretation negated scienter, even where an agent of a state Medicaid agency informed the defendant that it had billed the state for amounts to which it was not ultimately entitled because of a regulation excluding the particular class of providers from eligibility for the claimed payment.[105] The Court held that the civil servant's interpretation of the regulation did not put the defendant on notice that the defendant had received an overpayment, and that the defendant, therefore, did not have an overpayment liability until it received *formal* notice of its obligation to repay the claim.[106] This meant that it had no reverse FCA liability for failing to return the payment prior to receipt of such notice.[107] In so holding, the Court explained that in order for the relator to prevail in an assertion that the defendant knew of the overpayment, the relator "must show that *there is no reasonable interpretation* of the law that would make the allegedly false statement true."[108] Similarly, another court explained that if a defendant's determination that the defendant does not have overpayment liability is "based on a reasonable interpretation of a statute," failure to return payment:

> cannot support a claim under the FCA if there is no authoritative contrary interpretation of that statute. That is because the defendant in such a case could not have acted with the knowledge that the FCA requires before liability can attach . . . . It is hard to see how [the relators] could . . . have satisfied even the loosest standard of knowledge [under the FCA], i.e., acting in reckless

103. *Id.* at 880.

104. *Id.*

105. Olson v. Fairview Health Servs. of Minnesota, 831 F.3d 1063, 1070–71 (8th Cir. 2016).

106. *See id.* at 1074.

107. *Id.*

108. *Id.* at 1070 (emphasis added).

> disregard of the truth or falsity of the information, *when the relevant legal question was unresolved.* And we agree with the Ninth Circuit's holding that a defendant does not act with the requisite deliberate ignorance or reckless disregard by tak[ing] advantage of a disputed legal question.[109]

In these cases, the defendant has succeeded in arguing that an inability to trust the government's own statements as current or definitively correct precludes the defendant from having the requisite scienter. If this approach was to be applied fully and consistently, it would seem that defendants would seldom be seen as having the requisite scienter. Recognizing this problem, other courts have taken a different approach, explaining that this type of approach:

> would put an impossible burden on the drafters of statutes, regulations, and government contracts to avoid all potential ambiguity in order to prevent intentional fraud against the government; it would incentivize the intentional twisting of language in order to find profitable erroneous interpretations of the controlling text, even though all those subject to the text were well-aware of its intended meaning.[110]

Given that many CMS requirements can be construed as ambiguous, at least to some degree, we are left with a widespread failure to identify what objective facts (e.g., what guidance, from whom) indicate the government's subjective determination of materiality with sufficient clarity and authority to put a defendant on notice that a requirement is, indeed, material. What has emerged, therefore, is a messy and inconsistent body of case law that is out of touch with the reality of the health care industry's experience with Medicare's programmatic rules and leaves both relators and defendants with little predictability as to whether a claim will succeed.

D. (Mis)Application of Escobar's Materiality Standard in Healthcare FCA Cases

1. Courts Struggle to Assess Evidence of Materiality

In post-*Escobar* FCA cases, the question arises of how the government or a relator will demonstrate that a given requirement was material to payment. Courts applying *Escobar* to the plethora of statutes, regulations, and sub-regulatory guidance that govern federal

109. United States ex rel. Chilcott v. KBR, Inc., No. 09-CV-4018, 2013 WL 5781660, at *1 (C.D. Ill. Oct. 25, 2013); Safeco Ins. Co. of Am. v. Burr, 551 U.S. 47, 70 n.20 (2007) (when "the statutory text and relevant court and agency guidance allow for more than one reasonable interpretation, it would defy history and current thinking to treat a defendant who merely adopts one such interpretation as a knowing or reckless violator.").

110. Chilcott, 2013 WL 5781660, at *7.

healthcare reimbursement have had difficulty identifying compelling evidence of materiality.[111] The focus seems, by and large, to be on the government's behavior with respect to other instances of the same or similar non-compliance.[112] This opens up the question of what and whose behavior is relevant. When courts have settled on particular instances of behavior as indicators of materiality, it is apparent they often have been unable to interpret the government's behavior correctly, attaching undue significance to ancillary, technical requirements, while failing to recognize the import of requirements that go to the heart of the value of the items or services billed.

This struggle originates from the fact that *Escobar* applies common-law fraud principles that are designed to assess an individual's likely state of mind regarding claims involving complex government agencies. Traditional approaches to establishing materiality for purposes of a common law fraud rely essentially on the fact finder's subjective determination of what the defendant knew, or should have known, about the wronged party's state of mind.[113] This inquiry becomes mind-bogglingly abstract where the wronged party is the government. CMS employs 6,000 individuals across sixteen offices, six centers, and three consortia.[114] To administer the Medicare program alone, CMS contracts with sixteen independent Medicare Administrative Contractors to adjudicate Medicare claims, each of which employs thousands of employees.[115] CMS also contracts with state agencies to perform certain functions, including surveying providers to determine whether they meet the requirements for participation in CMS programs.[116] CMS publishes four paper-based Manuals and twenty-five internet-based Manuals, each hundreds (if not thousands) of pages in length, that articulate requirements and guidelines for CMS reimbursement, ranging from technical requirements for online claims submission to rules

111. *See* cases discussed in this Section II.C.

112. *See, e.g.*, United States v. Brookdale Senior Living Communities, Inc., 892 F.3d 822, 831–4 (6th Cir. 2018); *Ruckh*, 304 F. Supp. 3d at 1260–61; United States *ex rel.* Harman v. Trinity Indus. Inc., 872 F.3d 645, 661–63 (5th Cir. 2017); United States v. Sanford-Brown, Ltd., 840 F.3d 445, 447–8 (7th Cir. 2016).

113. *Escobar*, 136 S. Ct. at 1999–2000.

114. *See CMS Organizational Chart,* CMS.GOV (Dec. 9, 2019), https://www.cms.gov/About-CMS/AgencyInformation/CMSLeadership/OrganizationalChartASP.html [https://perma.cc/RA9K-3JUL].

115. *What is a MAC*, CMS.GOV. (Oct. 26, 2017), https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC [https://perma.cc/X94D-K5H5].

116. CTR. FOR MEDICARE & MEDICAID SERV., STATE OPERATIONS MANUAL, Pub. No. 100-07, Ch. 1 (Rev. Oct. 3, 2014) [https://perma.cc/E9J5-UWY4].

against patient abuse.[117] The Manuals are continuously updated and clarified through hundreds of annual transmittals.[118] CMS also issues numerous FAQs, training materials, letters, and memoranda that clarify requirements, and, in some cases, create new requirements.[119] When reimbursement requirements are clearly articulated, the application of such rules is often a matter of degree, with different CMS decision-makers drawing nuanced, and sometimes conflicting, decisions as to the line at which the frequency or pervasiveness of noncompliance becomes significant. It comes as little surprise, therefore, that courts have struggled to identify which requirements the collective CMS subjectively views as material.

The inability of courts to ascribe a mindset to CMS has contributed to, if not driven, the inconsistent and unpredictable outcomes of healthcare FCA cases. Take, for instance, the question of whether a rule can be considered material for FCA purposes if CMS continues to pay claims, despite knowledge that the rule has been violated. In one post-*Escobar* case, the court came to the seemingly intuitive conclusion that the fact that the government had continued to pay claims despite knowledge of regulatory non-compliance was essentially dispositive as to the issue of materiality.[120] In addressing a nursing home's failure to adhere to the regulatory requirement that plans of care be maintained for patients, the court concluded that there was a lack of evidence that the government considered the non-conformance material:

> [O]ne might expect evidence of whether record-keeping deficiencies have resulted in the sudden and indefinite discontinuation of payment to providers of health care services . . . evidence of whether governments are content—assisted by a regime of rigorous and regular inspections, audits, and accounting— to permit record-keeping practices that largely achieve the ends of, but differ from, the prescribed record-keeping; or evidence otherwise establishing the historical response of government to a long-standing non-compliance by a large

117. *Manuals*, CMS.GOV (May 28, 2019), https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/index?redirect=/Manuals [https://perma.cc/X8Q4-5XQ2].

118. *See Transmittals*, CMS.GOV. (Dec. 31, 2019), https://www.cms.gov/Regulations-andGuidance/Guidance/Transmittals [https://perma.cc/4VDX-JYVU].

119. CMS FAQs and other documents are generally found on the CMS website, organized by subject. FAQs and presentations may be linked at the bottom of topic-specific pages. *See Regulations & Guidance*, CMS.GOV, https://www.cms.gov/Regulations-and-Guidance/Regulations-and-Guidance [https://perma.cc/PQ8E-XGYA] (linking to numerous subpages by "provider type" or "special topic," each containing links to additional guidance).

120. *Ruckh*, 304 F. Supp. 3d at 1261.

> provider of services in a pervasively regulated and monitored industry . . . [121]

In the absence of such evidence, the court held that it appeared "that the federal and state government regard the disputed practices with leniency or tolerance or indifference or perhaps with resignation to the colossal difficulty of precise, pervasive, ponderous, and permanent record-keeping in the pertinent clinical environment."[122] Indeed, even though the government knew about the alleged violations, "evidence shows not a single threat of non-payment, not a single complaint or demand, and not a single resort to an administrative remedy or other sanction for the same practices that result in the enormous verdict at issue."[123] In that context, the court noted, even if the requirement could be considered material, "establishing the defendants' knowledge of materiality seems at least impractical, if not impossible."[124] Under this approach, continued payment in the face of knowledge of non-compliance appears to be essentially dispositive evidence of the lack of materiality, if not also to the scienter of the defendant.[125]

Other cases, however, have taken a different position, holding that continued payment in the face of apparent knowledge is not dispositive as to the issue of materiality and implying that continued payment may simply be indicative of a lack of knowledge on the part of the "right parties."[126] For example, a recent Fifth Circuit case acknowledged that continued payment by their government may be probative, but ultimately that "there are and must be boundaries to government tolerance of a supplier's failure to abide by its rules."[127] Citing a Ninth Circuit opinion, the court held that "questions of materiality remained even where the . . . [agency] had continued to pay."[128]

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121. *Id.* at 1264.

122. *Id.* at 1260.

123. *Id.* at 1260–61.

124. *Id.* at 1261.

125. Also, notable is the specter raised by this Court that non-payment may be too radical a response to minor infractions and, even if warranted, that it may be an impractical response because of the effect that non-payment could have on the availability of services to beneficiaries.

126. *See infra*, notes 130–31.

127. United States *ex rel.* Harman v. Trinity Indus. Inc., 872 F.3d 645, 664 (5th Cir. 2017).

128. *Id.* at 664. The observation that the FDA pays for claims is an error and raises a significant issue. *Campie* dealt with CMS payment for a drug approved by the FDA under allegedly-false pretenses. This error is typical of the confusion that courts have in dealing with Medicare and Medicaid-related issues. Even the *Campie* court seems not to have fully grasped, or at least not to have grappled with, the question of whether knowledge on

In another post-*Escobar* case, the court held that the fact that the relators had alleged that HHS OIG prosecutors had taken criminal and civil enforcement actions against providers who engaged in similar conduct was sufficient to raise a reasonable inference that CMS would deny payment if it knew about defendants' alleged violations.[129] In that case, the relators alleged that the defendants had submitted claims for services that were not reimbursable because they lacked required physician certifications.[130] The relators cited, and the court found persuasive, enforcement actions taken by prosecutors against other providers as evidence that certain physician certification requirements were material to CMS's decision to pay a claim.[131] In yet another post-*Escobar* case, the court explained that the Fifth Circuit's "approach to materiality" is that "the FCA requires proof only that the defendant's false statements 'could have' influenced the government's pay decision or had the 'potential' to influence the government's decision, not that the false statements actually did so."[132]

In the absence of any allegation that the government knew about a defect, or where the reviewing court does not accept payment or non-payment in the face of knowledge as dispositive, other factors can come into play and the analysis becomes even more complex and unpredictable. For example, in the context of a motion to dismiss, the Sixth Circuit engaged in a holistic analysis where no one factor was dispositive.[133] Specifically, in determining the materiality of a regulatory

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the part of one government agency (FDA) can be attributed to another (CMS), for purposes of discerning materiality. As stated by the Relator, its theory "of liability is that Gilead defrauded the FDA into approving the use of Synthetics China. The complaint alleges that out of three validation lots, two were hopelessly contaminated. There is no reasonable prospect that, had Gilead disclosed the actual test results, the FDA would have approved a facility so incapable of producing acceptable product. No allegation in the complaint suggests otherwise. Without this fraud, every pill containing FTC from Synthetics China would not have conformed to the NDA and thus would have been ineligible for reimbursement." Brief in Opposition at 15, Gilead Sciences, Inc. v. United States *ex rel* Campie, 139 S. Ct. 783 (2019) (No. 17-936). But, of course, FDA does not make reimbursement decisions; CMS does, so the relevant question is not whether FDA kept paying in the face of its knowledge of the problem, but whether CMS even knew about this issue.

129. United States *ex rel.* Lemon v. Nurses to Go, Inc., 924 F.3d 155, 162 (5th Cir. 2019).

130. *Id.* at 161.

131. *Id.* at 162.

132. *Trinity Indus. Inc.,* 872 F.3d at 661.

133. United States v. Brookdale Senior Living Communities, Inc., 892 F.3d 822, 831 (6th Cir. 2018). The court explained as follows:

requirement related to home health services, the court endeavored to determine whether the requirement went to the "essence of the bargain" between the parties.[134] In furtherance of this analysis, the court cited guidance documents that underscored the importance of the standard at issue, including documents that were not in effect at the time that the defendant provided or billed for the services, as evidence of the materiality of the requirement.[135] The court also dismissed as not probative of the question of materiality the government's decision not to intervene in the case (*i.e.*, to allow the whistleblower to proceed with the case without the government's involvement).[136] Lost in the vast and

> "[A] misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable under the False Claims Act." *Escobar*, 136 S. Ct. at 2002. The Act defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). In *Escobar*, the Supreme Court clarified this materiality requirement and emphasized that the "standard is demanding." 136 S. Ct. at 2003. "[M]ateriality 'look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation.'" *Escobar*, 136 S. Ct. at 2002 (second alteration in original) (quoting 26 SAMUEL WILLISTON & RICHARD A. LORD, A TREATISE ON THE LAW OF CONTRACTS § 69:12 (4th ed. 2003)). Something is material if a reasonable person "would attach importance to [it] in determining his choice of action in the transaction" or "if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter 'in determining his choice of action,' even though a reasonable person would not." *Id.* at 2002–03 (alteration in original) (quoting RESTATEMENT (SECOND) OF TORTS § 538 (AM. LAW INST. 1977)). The analysis of materiality is "holistic." United States ex rel. Escobar v. Universal Health Servs., Inc., 842 F.3d 103, 109 (1st Cir. 2016). Relevant factors include: (1) "the Government's decision to expressly identify a provision as a condition of payment"; (2) whether "the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement" or if, with actual knowledge of the non-compliance, it consistently pays such claims and there is no indication that its practice will change; and (3) whether the "noncompliance is minor or insubstantial" or if it goes "to the very essence of the bargain." *Escobar*, 136 S. Ct. at 2003 & n.5. None of these considerations is dispositive alone, nor is the list exclusive.
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> *Id.* at 2001–04.

134. *Id.*

135. *Id.* at 835–36.

136. *Id.* at 836. A pre-*Escobar* case that sought to establish materiality is also instructive and suggests that establishing materiality may require

ever-changing wilderness of CMS guidance, the Sixth Circuit appears to have assigned weight to government action (or inaction) at random, ultimately holding the defendant responsible for divining a state of mind that the government itself had not yet fully expressed.

2. Impossibility of Assessing the Government's State of Mind

These decisions add little to our understanding of materiality. Rather, they underscore the impossibility of understanding the intention of the multi-headed hydra that is the government. Trying to divine the government's state of mind is problematic. Other than through properly-adopted law, the government does not speak with one voice or act with a unitary objective. *Escobar* requires that we do not automatically give deference to a law's own statement that it is a condition of payment, but that we instead must look elsewhere for evidence of materiality—but it does not tell us where to look.

The mind of the "reasonable man" is knowable with reference to our shared experience as humans, in a way that the government's "state of mind," if it can be said to have one, is not. By way of analogy: the law has long struggled with how to ascertain the state of mind of corporations, such that they can be said to knowingly engage in securities fraud misrepresentation, with the Circuits advancing a number of different theories as to how it can be assessed.[137] Ultimately, these theories, not surprisingly, all concentrate on assessing the mindset of a particular corporate actor.[138] With regard to securities fraud, for example, some courts focus on the scienter of the particular corporate official or officials who make or issue the statement, disregarding the state of mind of other corporate agents, holding, for example, that

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testimony from suitable agency representatives to the effect that the standard is material. In that case, the court explained:

> In this case . . . record evidence could have allowed the jury to conclude that the contract's conflict of interest provisions were far from minor . . . '[n]umerous witness[es] from both the NRC and SAIC testified that the [organizational conflict of interest] obligations in SAIC's contracts with the NRC were important to the overall purpose of the contract.' NRC contracting officers and specialists also testified that had they been aware of SAIC's apparent or actual conflicts, such as its relationships with British Nuclear and Bechtel Jacobs, they would not have awarded the two contracts, nor would they have made payments under those contracts.

United States v. Sci. Applications Int'l Corp., 626 F.3d 1257, 1271 (D.C. Cir. 2010).

137. *See, e.g.*, In re Omnicare, Inc. Sec. Litig., 769 F.3d 455, 473 (6th Cir. 2014) (explaining that "state of mind" analysis is more complicated when the defendant is a corporation).

138. *See id.*

person must know of the falsity of the statement she makes.[139] Other courts have allowed the statement to be considered false when it appears that corporate officials must have known that the statements were false, even where the person speaking them did not.[140] Regardless of the approach taken, the objective ultimately becomes (in many cases, out of necessity) to ascertain the subjective state of mind of a living person with authority to represent the corporate will.

Notably, in securities fraud cases, the task is simpler, as the alleged misrepresentation is a clear affirmative act manifesting a specific position (and not just the routine act of payment or non-payment, where the reasons for the decision may not be evident). There is, moreover, some consensus between courts as to who has authority to speak on behalf of the corporation (likely those individuals who control the corporation, such as executives, the board of directors, or majority

139. In re Apple Computer, Inc. Sec. Litig., 243 F. Supp.2d 1012, 1023 (N.D. Cal. 2002), *aff'd* 127 Fed. Appx. 296 (9th Cir. 2005) (citing Nordstrom v. Chubb & Son, 54 F.3d 1424, 1435–36 (9th Cir. 1995)).

140. Joseph M. McLaughlin, *Corporate Litigation: Pleading Corporate Scienter: Circuits Split on Standard*, SIMPSON THACHER 1-2 (2014), http://www.stblaw.com/docs/default-source/Publications/ny-law-journal_joe-mclaughlin_corporate-litigation-column_12_11_2014.pdf [https://perma.cc/WP2V-T5Y8]. As one commenter explained:

> In adopting this respondeat superior approach to corporate scienter, the Fifth Circuit . . . explained that its view is consistent with the common law rule that "where, as in fraud, an essentially subjective state of mind is an element of a cause of action also involving some sort of conduct, such as a misrepresentation, the required state of mind must actually exist in the individual making (or being a cause of the making of) the misrepresentation, and may not simply be imputed to that individual on general principles of agency". . . . The Fifth Circuit explicitly rejected the notion that corporate scienter could stem from the "collective knowledge [of the corporation's agents] . . . " where no identified individual possessed the requisite state of mind . . . . In contrast, the Second, Seventh and Ninth Circuits have each adopted . . . [the view that it is sufficient that the facts] creat[e] a strong inference that someone whose intent could be imputed to the corporation acted with the requisite scienter. . . . The U.S. Court of Appeals for the Seventh Circuit [explained] . . . that "it is possible to draw a strong inference of corporate scienter without being able to name the individuals who concocted and disseminated the fraud." To illustrate the point, the court posited a stark hypothetical: If General Motors announced that it sold one million SUVs in a particular year when the actual number was zero, "[t]here would be a strong inference of corporate scienter, since so dramatic an announcement would have been approved by corporate officials sufficiently knowledgeable about the company to know that the announcement was false."
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> *Id.*

owners). Most fundamentally, we do not know, who, post-*Escobar,* has the authority to speak for the government.

The conundrum of ascribing a unified and knowable state of mind to the government may have led to the apparent reliance of *Escobar* and its progeny on payment decisions as indicators of materiality. However, the fact that courts have failed to treat with meaningful consistency the government's decision to act, or not to act, to pay or recoup payment in the face of knowledge of non-compliance only further highlights that even seemingly straightforward indicators of the government's state of mind can be remarkably complex and convoluted in practice. Indeed, "material to payment" (*i.e.*, that non-compliance has the capacity to, and probability of, influencing payment) is not, in practice, synonymous with "important" or even "vital" to payment. Indeed, in many cases, CMS may care quite a bit about a given rule despite the fact that, as a practical matter, CMS would not withhold payment if that rule was violated, meaning that such rule never had the capacity to influence payment. Particularly in the context of federal health care programs, the decision to pay or not to pay could be expected to be influenced by a variety of considerations unrelated to the pure import of the non-compliance, such as the fact that patients would be harmed by withholding payment, balancing of resources to enforce the rule, or other policy considerations relevant to a particular product, service, or program. From this perspective, whether a particular failing is actually material is highly contextualized, and might vary from provider to provider, depending on the decision-maker, the times, the degree of non-compliance, and the perceived impact of non-payment on Medicare beneficiaries. Some facilities may simply be "too big to fail,"[141] while others may find themselves on thin ice due to historically poor relationships with government-contracted surveyors and auditors. Setting aside the equitable issues in such a disparate approach, but acknowledging its reality, the fact that CMS approaches payment on a provider-by-provider and situation-by-situation basis, CMS's disparate treatment of providers may limit the ability to establish the existence of materiality by reference to the government's conduct from provider to provider.

Another complicating factor is the question of which of the many levels and representatives of "government" involved in the administration of the programs have the authority to make determinations regarding materiality. This issue is most evident when considering whether the standard goes to the essence of the bargain. Whose opinions must a provider consider relevant and who may testify

141. *See, e.g., Ruckh*, 304 F. Supp. 3d at 1264 (citing the large size of the provider and the fact that it provides an essential service to a large population, who could not otherwise access the service as relevant counter-weights to an assertion of materiality, in that they suggest that non-payment may not be the expected response to non-conformance).

as to the state of mind of the government? Must an official be acting within the scope of her authority in making the decision to pay or not to pay?[142] In one particularly stunning case, the relator advanced the proposition that the oral opinions of an employee of the state Medicaid agency were sufficient to establish that a given requirement was material to CMS's decision of whether or not to pay a claim. [143] It is, moreover, unclear to what degree the opinions of Medicare Administrative Contractors ("MACs"), Administrative Law Judges ("ALJs"), the HHS Department's Appeal Board, the HHS Office of Inspector General ("OIG"), or any given governmental official are relevant to a determination of materiality. It is also unclear how, if these opinions were relevant to such a determination, one could reconcile such significance with the principle, applicable to ALJ Opinions[144] and OIG Opinions,[145], that they do not bind third-parties,

142. *See, e.g.*, Memorandum from the Deputy Att'y Gen. to All Component Heads and U.S. Attorneys on Bringing Criminal Charges Against Corporations (June 16, 1999), https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2010/04/11/charging-corps.PDF [https://perma.cc/4XGX-83Y2].

143. *See* Olson v. Fairview Health Servs. of Minnesota, 831 F.3d 1063, 1073–74 (8th Cir. 2016).

144. Medicare ALJ Opinions do not have precedential effect. However, the Chair of the Department of Health and Human Services Departmental Appeals Board ("DAB Chair") may designate a final decision issued by the Medicare Appeals Council as precedential. 42 C.F.R. § 401.109(a) (2019). In adopting this rule, the government explained: "Individual determinations and decisions by CMS contractors, OMHA ALJs, and the Council currently are not precedential and have no binding effect on future initial determinations (and equivalent determinations) or claims appeals. We did not propose to change the non-precedential status and non-binding effect on future initial determinations (and equivalent determinations) or claim appeals of any determinations or decisions except as to Council decisions designated as precedential by the DAB Chair." Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures, 82 Fed. Reg. 4974, 4978 (Jan. 17, 2017).

145. *See* Zimmer, Inc. v. Nu Tech Medical, Inc., 54 F. Supp. 2d 850, 855 (N.D. Ind. 1999) ("Pursuant to 42 U.S.C. § 1320a-7d(b), the Secretary of the Department of Health and Human Services, in consultation with the Attorney General, is authorized to issue advisory opinions on specific topics, including what constitutes prohibited remuneration under § 1320a-7b(b), and whether any activity or proposed activity could result in imposition of sanctions or exclusion from participation in federal health care programs. *See* 42 U.S.C. § 1320a-7d(b)(2). An advisory opinion issued by the Secretary binds the Secretary and the party or parties requesting the opinion. 42 U.S.C. § 1320a-7d(b)(4)(A). A party's failure to seek or join a request for an advisory opinion may not be used as evidence to prove that the party intended to violate federal health care statutes. 42 U.S.C. § 1320a-7d(b)(4) (B)."). "An advisory opinion issued

or the principle, applicable to MACs, that, as non-governmental bodies, they have limited authority.[146]

There is, moreover, the fact that the government's view of a particular requirement may not be static. The OIG, for example, issues Opinions relating to whether or not particular arrangements are compliant with AKS. One can imagine that an Opinion suggesting that a certain type of arrangement implicated the AKS would be relevant to showing that the government viewed conformance with these "requirements" as material to AKS compliance, and thus, ultimately, as material to payment. Setting aside, for a moment, the problem of whether such an inference is warranted, and further, whether the Opinion should be admissible, there is the problem of changing views expressed through the Opinion process. For example, in one case:

> OIG originally issued [the requester] PSI an advisory opinion on April 4, 2002, covering PSI's proposed arrangement to subsidize the medical care costs of 'financially needy Medicare beneficiaries.' Following publication of the 2014 PAP [Patient Assistance Program] Bulletin, however, OIG informed PSI [as it did other PAPs with advisory opinions that were inconsistent with the 2014 PAP Bulletin] that, in light of the concerns reflected in that guidance document, OIG would require certain changes for PSI to retain its favorable advisory opinion. This set off a lengthy negotiation process between OIG and PSI, which lasted for more than two years, over the facts that PSI would

by the OIG will have no application to any individual or entity that does not join in the request for the opinion. No individual or entity other than the requestor(s) may rely on an advisory opinion." 42 C.F.R. § 1008.53 (2019). *See also* Def.'s Mem. Supp. Mot. for Leave to Take Disc., Patient Services, Inc. v. United States, No. 3:18-cv-0016, at 2 (E.D. Va. July 18, 2018), https://www.druganddevicelawblog.com/wp-content/uploads/sites/30/2018/07/Patient-Services-OIG-Motion.pdf [https://perma.cc/WP7H-2BCW] ("OIG is an independent and objective oversight unit created to carry out the mission of preventing fraud and abuse and promoting economy, efficiency, and effectiveness of HHS programs and operations. See 5 U.S.C. App. 3 § 2 (Inspector General Act of 1978). One of its functions is to issue, in consultation with the Department of Justice ("DOJ"), written advisory opinions regarding the interpretation and application of certain statutory provisions designed to deter fraud and abuse in the referral of federal healthcare program beneficiaries (such as Medicare and Medicaid recipients) to particular medical goods and services. See 42 U.S.C. § 1320a-7d(b.).").

146. *See, e.g., What is a MAC*, CMS.GOV (Dec. 13, 2019), https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/What-is-a-MAC#WhatIsAMac [https://perma.cc/VC4Y-9JS3].

> need to certify as true in order to retain its favorable advisory opinion.[147]

Here, the view of the government as to what was required for AKS compliance was malleable, and ultimately, negotiable. Assuming that the OIG's position on conformance with the AKS could be admissible and relevant evidence of the government's determination of materiality, which of these positions would be the relevant one, and for what time period?

The problem of tracking the government's evolving view of its own requirements comes into sharp relief when one considers the dilemma of a healthcare provider's assessment of whether or not she has reverse false claims liability. Under the FCA, a person can be liable for a "reverse false claim" if she submits a claim with good intent, but later becomes aware that the claim is legally false at the time it was paid, such that she we not entitled to payment and fails to timely return the overpayment to the government.[148] To determine whether or not a payment was made for a legally false claim, the defendant must assess any identified non-conformance with law and decide whether or not it would have been considered material by the government at the time that the claim was submitted, which may be many years prior to the assessment.[149] The retrospective nature of this inquiry raises some additional questions. For example, how can the provider establish the government's actual view of the issue as of the relevant time? Of what relevance are actions of the government that post-date the submission date? How is one to distinguish a recently-articulated view of materiality from a recently-evolved view of materiality? How would a provider demonstrate what he or she knew of these indicators at the time of submission of the claim?

The problems posed by the government's inability to articulate clear and consistent expectations is more than merely hypothetical or philosophical; it creates real confusion for healthcare providers who often find themselves having to decide, based on unclear and inconsistent instructions, whether large sums of money must be returned to CMS. As well, as noted above in Section II.B, a similar problem pervades the question of when a standard has been expressed

147. Def.'s Mem. Supp. Mot. for Leave to Take Disc., No. 3:18-cv-0016, at 5.

148. 31 U.S.C. § 3729 (2018) ("[T]he term 'obligation' means 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 . . . .").

149. *See, e.g.,* 42 C.F.R. § 401.305(e)-(f) (2019) (requiring that any overpayment must be reported and returned if a person identifies an overpayment within six years of the date it was received).

with sufficient clarity and finality to cause the defendant to have scienter.

Adopting the view that the government holds a knowable, consistent, and unitary view of materiality, while at the same time disregarding the only objective expression of that view—the designation in a statute or regulation that it is a condition to payment—interferes with the predictable assessment of materiality, and, ultimately, FCA liability. Given the intensive involvement of multiple governmental agencies, state and federal actors, and private subcontractors in the administration of claims,[150] it is difficult to say if and when the government knew of non-conformance with any particular standard, at what point the government began to care, or if the government was, or would have been, inclined to condition reimbursement on compliance with a given standard.

3. OIG Treatment of Billing Non-Compliance as a Case in Point

Many of the difficulties in determining materiality are illustrated by the way the government has treated non-conformity with billing "requirements" for continuous positive airway pressure ("CPAP") supplies. CPAP supplies are meant to assist individuals who suffer from sleep apnea, a condition that results in an often-debilitating and dangerous inability to breathe while sleeping.[151] For a number of years, and on multiple occasions, the government has noted that Durable Medical Equipment ("DME") suppliers are overwhelmingly non-compliant with a variety of Medicare requirements relating primarily to documentation of medical necessity.[152] In the face of this

150. For example, one court held that the government's reimbursement of prescription drugs for off-label uses "does not establish that the requirement [prohibiting off-label use] is immaterial as a matter of law." United States v. Celgene Corp., 226 F. Supp.3d 1032, 1050 (C.D. Cal. 2016). Similarly, "[t]he fact that the FDA knew generally about off-label use does not mean CMS knew about and agreed to reimburse particular off-label claims." *Id.* And "the fact that CMS included off-label uses of [a drug] in a program designed to expand the scope of Medicare's prescription drug coverage on a temporary basis and for a limited number of patients does not show that CMS was willing to pay for these uses more generally." *Id.*

151. John Donovan, *How to Sleep Easier with your CPAP Machine,* WEBMD (May 2, 2016), https://www.webmd.com/sleep-disorders/sleep-apnea/features/cpap-machine [https://perma.cc/BA92-C4DH].

152. *See, e.g.*, OFF. INSPECTOR GEN., DEP'T OF HEALTH & HUM. SERV., OIE 04-99-00670, MEDICAL EQUIPMENT SUPPLIERS: COMPLIANCE WITH MEDICARE STANDARDS (2001), https://oig.hhs.gov/oei/reports/oei-04-99-00670.pdf [https://perma.cc/44A6-CN25] (concluding that over fifty percent of suppliers did not comply with a consumer information standard, but recommended responses to not include non-payment). "The OIG issued a report in August 2008 regarding an audit of CMS' medical review of DME

acknowledged wide-spread non-compliance, the government has, by and large, continued to pay claims for CPAP supplies, and, at least on one occasion, has suggested that the appropriate response to broad-based non-compliance with these and similar standards is something other than non-payment.[153] A reasonable DME supplier could, thus, conclude that the government, through its inaction and statements, has conceded that compliance with these standards is not a material condition of payment.

Notwithstanding this observation, in late 2018, OIG took action to retrieve payments from CPAP suppliers. It conducted a study of CPAP billing and found that many claims were for services "that durable medical equipment suppliers submitted for replacement positive airway pressure (PAP) device supplies [that] did not comply with Medicare requirements."[154] It then summarily observed that: "On the basis of our sample results, we estimated that Medicare made overpayments of almost $631.3 million for replacement PAP device supply claims that did not meet Medicare requirements."[155]

Even though the OIG report merely assessed compliance with a variety of statutory, regulatory, and sub-regulatory standards and provided no analysis to support its conclusion that non-compliance with any, or all, of these standards was a material condition of payment, the report seemed to assume that all payments made in the face of any non-compliance with any of the considered standards were overpayments.

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claims paid by Medicare in fiscal year 2006. Based on its review of a sample of DME claims, the OIG estimated that the Medicare payment error rate was 28.9 percent. In other words, almost 30 percent of the DME claims reviewed were erroneously paid by the Medicare program. In its report, the OIG noted that 'Medicare claims from DME suppliers have historically been more vulnerable to billing fraud and abuse than claims from other providers because of weak Medicare payment controls. It recommended that, in reviewing DME claims, 'CMS obtain all medical records (including, but not limited to, physician's records) for DME claims and contact the beneficiaries named on high-risk claims.' In its Semi-Annual Report to Congress, the OIG further highlighted the recommendation that CMS have its contractors 'review all available supplier documentation and all medical records necessary to determine compliance with applicable requirements on medical necessity.'" Tom Herrmann, *Durable Medical Equipment (DME) Documentation Required for Medicare Payment*, STRATEGIC MGMT. SERV. (Jan. 2009), https://compliance.com/publications/durable-medical-equipment-dme-documentation-required-for-medicare-payment/ [https://perma.cc/RC4Q-M9ZZ].

153. HHS OFF. OF INSPECTOR GEN., MOST MEDICARE CLAIMS FOR REPLACEMENT POSITIVE AIRWAY PRESSURE DEVICE SUPPLIES DID NOT COMPLY WITH MEDICARE REQUIREMENTS (June 7, 2018), https://oig.hhs.gov/oas/reports/region4/41704056.asp [https://perma.cc/3T54-7SHL].

154. *Id.*

155. *Id.*

In other words, by deeming the entire universe of uncovered errors as resulting in "overpayments," the OIG report appears to assert that CMS both could and should recoup payment for all such claims and that to retain such overpayments could result in reverse FCA liability for CPAP suppliers. Should a CPAP supplier understand from this that the OIG's statement represents an accurate view of the government's position regarding the materiality of each such standard? If so, must the supplier promptly repay amounts relating to any claims that exhibit the deficiencies cited by the OIG or face reverse FCA liability? Or, should the supplier understand, as seems more likely to be the case, that the OIG simply conflated, without much thought as to legal significance, any degree of non-conformance with the existence of an of overpayment that must be returned by the supplier? However, at odds with the practices of CMS, OIG seems to have assumed that the correct response for non-compliance with any standard whatsoever is non-payment. Instead of intending a sweeping profession of the materiality of all CPAP billing requirements, however, it seems more likely that the OIG simply failed to think through the import of the terminology that it chose to describe the extent of non-compliance in the billing of CPAP supplies.

More recently, OIG conducted a similar inquiry into non-compliance with Medicare "documentation requirements" for inhalation drugs (drugs breathed directly into the lungs, such as inhalers for asthma and chronic obstructive pulmonary disease).[156] The documentation standards in question supported certain statutory requirements but were derived from an LCD and CMS's sub-regulatory *Medicare Program Integrity Manual*.[157] These were that:

> For an inhalation drug to be eligible for Medicare reimbursement, the supplier must have a signed, detailed written order from the prescribing physician; proof of delivery; and, for refills of the original order, a documented refill request. The supplier must contact the beneficiary before dispensing a refill to (1) ensure that the refilled item remains reasonable and necessary and that existing supplies are approaching exhaustion and (2) confirm any changes or modifications to the order. The supplier must also maintain timely documentation to support that the inhalation drug continues to be used by the beneficiary.[158]

On the basis of non-compliance with these requirements, OIG "estimated that $92.5 million of the $259.5 million paid to suppliers for

156. DEP'T OF HEALTH & HUMAN SERVS., OFF. INSPECTOR GEN., A-09-18-03018, MEDICARE IMPROPERLY PAID SUPPLIERS AN ESTIMATED $92.5 MILLION FOR INHALATION DRUGS (2019).

157. *Id.* at 3.

158. *Id.*

inhalation drugs was unallowable for Medicare reimbursement."[159] OIG "recommend[ed] that CMS instruct the Medicare contractors to recover $36,825 in overpayments for the 39 unallowable claim lines and notify the 22 suppliers associated with the 39 claim lines with potential overpayments of $36,825 so that those suppliers can exercise reasonable diligence to investigate and return any identified overpayments . . . "[160] OIG observed that there was a very high industry-wide rate of erroneous claims for these drugs, with the "Medicare fee-for-service improper payments reports for 2010 to 2018 (indicating) . . . that the improper payment rates ranged from 11 to 68 percent."[161]

As with the CPAP supplies, the OIG concluded that the inhalation drugs audit report constituted credible information of potential overpayments with the consequence that suppliers that received notification of these potential overpayments were subject to potential overpayment liability under the FCA if they did not "(1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify any overpayment amount over a six-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments (60-day rule)."[162] Some of the examples of non-conformance offered were minor, indicating that CMS likely received the benefit of its bargain in at least some of the cases in which OIG appeared to be demanding repayment:

> For example, Medicare paid a supplier $12,229 for providing treprostinil, an inhalation drug used to treat pulmonary arterial hypertension, to a beneficiary on November 7, 2017. For this sampled claim line, the supplier provided to us a delivery record showing that it had shipped the item to its retail store; however, the supplier did not provide us with the signed and dated delivery document verifying that the inhalation drug was delivered to the beneficiary.[163]

There is a marked lack of attention to an analytically-coherent approach to distinctions between material and immaterial payment requirements that permeates the Medicare payment scheme. Notably, the manner in which these OIG reports evidence slavish adherence to programmatic requirements without regard to considerations of materiality is often a feature of audits performed by commercial contractors, who simultaneously define CMS's day-to-day payment determinations, but also, as a matter of law, should not be permitted

159. *Id.* at 11.

160. *Id.* at 13.

161. *Id.* at n.2

162. *Id.* at 4.

163. *Id.* at 8.

to define the government's state of mind.[164] For example, it is not uncommon for contractor-employed auditors to insist on a provider refunding the entire amount of a claim for services that fail to comply with fairly picayune standards or requirements (such as narrowly missing a documentation timing requirement), without considering whether or not the government has received all or most of the value of the bargain.[165] On the other hand, there are contexts in which the existence of a systemic "error" rate appears to be acknowledged and accommodated as an inevitability. As noted above, the government has continued to routinely pay DME claims in the face of acknowledged, widespread non-compliance.[166]

In an even more explicit example of the government's acceptance of a structural rate of non-compliance in healthcare billing, for providers who are instructed to conduct period claims review under Corporate Integrity Agreements with OIG, OIG instructs that:

> If the net financial error rate of those . . . claims equals or exceeds 5 percent, then a full sample must be reviewed and a systems review must be conducted. The full sample must include a sufficient number of paid claims to yield results that estimate the overpayment in the population within a 90 percent confidence and 25 percent precision level.[167]

However, "[i]f the net financial error rate of the discovery sample is below 5 percent, the review is complete."[168] This is to say that, if a sample audit reveals a low but statistically-significant claims error rate, OIG, nonetheless, takes the position that the provider is not obligated to perform a full audit to root out and return overpayment, despite

164. *See generally What Is a MAC Audit?*, OBERHEIDEN, P.C. (Nov. 13, 2017), https://medicare-lawyer.com/mac-audit/ (explaining that medical practices may be subject to audit if the MAC identifies "'discrepancies' even in situations where the billing was reasonable, medically necessary, and within CMS policy")[https://perma.cc/V6P5-E6JV].

165. *See generally What Are Recovery Audit Contractors?*, AM. COLLEGE OF CARDIOLOGY, https://www.acc.org/tools-and-practice-support/practice-solutions/medicare-enrollment-and-claims-submission/recovery-audit-contractors/what-are-racs [https://perma.cc/648N-EZXP] (last visited Aug. 12, 2020) (explaining that recovery audit contractors are paid a contingency fee to find overpayments, so their motives may be more aligned with finding large overpayments rather than egregious violations of the law).

166. *See supra* notes 154–55 and accompanying text.

167. *Corporate Integrity Agreement FAQ*, DEP'T OF HEALTH & HUMAN SERVS., OFF. OF INSPECTOR GEN., https://oig.hhs.gov/faqs/corporate-integrity-agreements-faq.asp [https://perma.cc/2EHA-VMN6] (last visited Dec. 26, 2019).

168. *Id.*

knowledge of the error rate. These inconsistent approaches, both within OIG and between OIG and CMS, underscore the difficulty of deciding whether or not any given deviation is material, based on the government's behavior.

OIG's approach in the reports also does not consider the legitimacy of the standards against which it measured conformance.[169] What is the supplier to make of the fact that many of the standards considered by the OIG were not actually embodied in any statute or regulation, but, instead, were reflected only in non-authoritative LCDs or in other sub-regulatory guidance?[170] What of the fact that some of the standards were seemingly at odds with statutory and regulatory requirements?[171] Should the supplier understand that the government can, and has, somehow incorporated these sub-regulatory standards into its interpretation of a standard that is material to its payment decisions? Or, as seems more likely to be the case, should the supplier understand that the OIG simply assumed that the contractor standards were both authoritative and material, without engaging in legal analysis?

III. *AZAR V. ALLINA HEALTH SERVICES*

A. Under the Medicare Act, Substantive Rules Are Subject to Notice-and-Comment Rulemaking

While not an FCA case, the recent Supreme Court case, *Azar v. Allina Health Services*,[172] brings some much-needed clarity to the question of when the FCA can be used as a tool to hold providers accountable for compliance with the myriad of rules and regulations that attach to participation in the Medicare program, and, therefore, has broad-reaching implication for FCA cases going forward. *Allina* addressed the enforceability of a payment rule that was "promulgated" simply by publication on the CMS website without notice-and-comment.[173] The rule at issue in *Allina* changed a formula for calculating a payment due to hospitals related to the proportion of low income Medicare patients they served, and "dramatically—and retroactively—

169. *See, e.g.*, DEP'T OF HEALTH & HUMAN SERVS., *supra* note 156, at 13.

170. An LCD is a determination by a MAC respecting whether or not a particular item or service is covered on a contractor–wide basis in accordance with Section 1862(a)(1)(A) of the Act. 42 U.S.C. § 1395ff. The 2016 21st Century Cures Act included changes to the LCD adoption process, including requiring MACs to engage in certain notice-and-comment procedures with respect to LCDs. 42 U.S.C. § 1395y(l) (2018). These requirements are not, however, sufficient to meet the notice-and-comment requirements of the Medicare Act. 42 U.S.C. § 1395hh (2018). *See also supra*, notes 44–50 and accompanying text.

171. *See supra* notes 153–174 and accompanying text.

172. *Allina*, 139 S. Ct. at 1804.

173. *Id.* at 1808.

reduced payments to hospitals serving low-income patients."[174] While seemingly a narrow administrative law case, *Allina* deals with the ability of CMS to alter rights to payment through sub-regulatory guidance, and, therefore, ultimately sets boundaries on CMS's ability to withhold payment or demand repayment for non-compliance with programmatic rules.[175] As a result, *Allina* has significance for determinations that go to the heart of a substantial portion of FCA cases: whether non-conformance with a given CMS standard can be used as a predicate for FCA liability under a theory of legal falsity.

The core issue in *Allina* was whether or not the new payment rule was exempt from notice-and-comment requirements under the Medicare Act.[176] The Medicare Act, which ultimately governs all payments made under the Medicare program, contains a requirement that "substantive" rules (as opposed to "procedural" rules) be promulgated via formal notice-and-comment rulemaking.[177] The APA, on the other hand, which broadly governs the administrative rulemaking of federal agencies, provides that interpretive rules, along with procedural rules, and several other categories of rules, are exempt as a class from the procedural prerequisite of notice-and-comment rulemaking.[178] These exempted rules are accorded substantial legal effect via traditional deference analysis, which is predicated on the APA's grant of authority to agencies to adopt such rules.[179] HHS acknowledged the requirements of

174. *Id.*

175. *See generally id.*

176. *Id.* at 1810.

177. *Id.*

178. Section 553 of the APA exempts from the notice-and-comment process: rules involving military and foreign affairs; "matter[s] relating to agency management or personnel or to public property, loans, grants, benefits, or contracts"; "rules of agency organization, procedure, or practice"; interpretative rules and general statements of policy; and rules as to which the agency has good cause to conclude that notice-and-comment would be "impracticable, unnecessary, or contrary to the public interest." Administrative Procedure Act, 5 U.S.C. §553 (2006).

179. Under APA jurisprudence, interpretive rules are not themselves binding but constitute authoritative interpretations of binding law, via so-called "*Auer* deference" to agency interpretive authority. As a practical matter, this means that many interpretative rules are given substantial weight, which, in practice, has binding legal effect. The Supreme Court explained this dynamic in a recent case:

> Kisor [the plaintiff] . . . claims that *Auer* circumvents the APA's rulemaking requirements. Section 553, as Kisor notes, mandates that an agency use notice-and-comment procedures before issuing legislative rules. But the section allows agencies to issue "interpret[ive]" rules without notice-and-comment. A key feature of those rules is that (unlike legislative rules) they are not

the Medicare Act, but argued that its new payment rule simply articulated HHS's changed understanding of existing statutory requirements, and was, therefore, an "interpretive" rule, as defined under the APA.[180] HHS further argued that the term "substantive" did not incorporate valid interpretive rules, and that the Medicare Act was to be read in tandem with the APA.[181] As a result, HHS reasoned, Medicare interpretive rules were exempted from notice-and-comment requirements in the same manner as the interpretive rules of other agencies and programs are explicitly exempted from such requirements under the APA.[182] Thus, HHS argued, the rule was not subject to notice-

> supposed to "have the force and effect of law"—or, otherwise said, to bind private parties. Instead, interpretive rules are meant only to "advise the public" of how the agency understands, and is likely to apply, its binding statutes and legislative rules. But consider, Kisor argues, what happens when a court gives Auer deference to an interpretive rule. The result, he asserts, is to make a rule that has never gone through notice-and-comment binding on the public. Or put another way, the interpretive rule ends up having the "force and effect of law" without ever paying the procedural cost.
>
> But this Court rejected the identical argument just a few years ago, and for good reason. In *Mortgage Bankers*, we held that interpretive rules, even when given Auer deference, do not have the force of law. An interpretive rule itself never forms "the basis for an enforcement action"—because, as just noted, such a rule does not impose any "legally binding requirements" on private parties. An enforcement action must instead rely on a legislative rule, which (to be valid) must go through notice-and-comment. And in all the ways discussed above, the meaning of a legislative rule remains in the hands of courts, even if they sometimes divine that meaning by looking to the agency's interpretation. Courts first decide whether the rule is clear; if it is not, whether the agency's reading falls within its zone of ambiguity, and even if the reading does so, whether it should receive deference. In short, courts retain the final authority to approve—or not—the agency's reading of a notice-and-comment rule. No binding of anyone occurs merely by the agency's say-so.

Kisor v. Wilkie, 139 S. Ct. 2400, 2420 (2019) (internal citations omitted).

180. *Allina*, 139 S. Ct. at 1810–11.

181. *Id.* at 1811.

182. The APA, among other things, excepts from notice-and-comment "interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice." 5 U.S.C. § 553(b) (2018). The Medicare Act excepts only rules that are excepted by statute or that are promulgated under Section 553 of Title 5 (which governs rules related to a military or foreign affairs function of the United States, or a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts). 42 U.S.C. § 1395hh(3)(c) (2018).

and-comment requirements and should be accorded judicial deference.[183] The hospitals that challenged the rule argued that the rule was not procedural, but substantive, with the consequence that it required notice and comment to be effective.[184]

The Court rejected the government's argument that interpretive rules, as a class were excluded from the requirements applicable to substantive rules and concluded that the government had conceded that there was a statutory gap, in that the "rule" in question was not articulated in the statute. The Court held that "when the government establishes or changes an avowedly substantive 'gap'-filling policy, it can't evade its notice-and-comment obligations . . . on the strength of the arguments it has advanced in this case."[185] In other words, substantive rules promulgated by CMS, whether interpretive or not, are subject to notice and comment.[186] The Court appears to endorse, if

183. *Allina*, 139 S. Ct. at 1807 ("The government suggests the statute means to distinguish a substantive from an interpretive legal standard and thus tracks the Administrative Procedure Act (APA), under which 'substantive rules' have the 'force and effect of law,' while 'interpretive rules' merely 'advise the public of the agency's construction of the statutes and rules which it administers.' Because the policy of counting Part C patients in the Medicare fractions would be treated as interpretive rather than substantive under the APA, the government submits, it had no statutory obligation to provide notice and comment before adopting the policy.").

184. *Id.* at 1811 ("The hospitals suggest the statute means to distinguish a substantive from a procedural legal standard. On this account, a substantive standard is one that 'creates duties, rights and obligations,' while a procedural standard specifies how those duties, rights, and obligations should be enforced. Black's Law Dictionary 1281 (5th ed. 1979) (defining 'substantive law'). And everyone agrees that a policy of counting Part C patients in the Medicare fraction is substantive in this sense, because it affects a hospital's right to payment. From this it follows that the public had a right to notice-and-comment before the government could adopt the policy at hand." (emphasis added)).

185. *Id.* at 1817.

186. The Medicare Act gives the Secretary authority to prescribe regulations to administer Medicare at 42 U.S.C. § 1395hh(a)(2) (2018). That Section provides that any "rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter" must be promulgated by the Secretary by regulation. It then goes on to specify what is required in the way of notice-and-comment for such regulations, which includes the requirement that, with certain limited exceptions, "the Secretary shall provide for notice of the proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon." The 60-day requirement is twice the APA minimum of 30 days. 42 U.S.C. § 1395hh(c)(3) (2018).

not fully embrace, the traditional distinction between procedural and substantive rules advanced by the plaintiff hospitals.[187]

In contrast to the broad powers to articulate and enforce interpretive rules granted to federal agencies under the APA, the *Allina* Court held that the Medicare Act requires that *all* substantive rules that establish or change a standard governing the scope of benefits, the payment for services, or eligibility to furnish or receive Medicare-reimbursed services be promulgated through notice-and-comment rulemaking process.[188] As the agency has no authority to adopt so-conceived "substantive-interpretive" rules other than by regulation, any rule promulgated by CMS that is "substantive" (*i.e.*, that impacts a right to payment or benefits), including rules that would qualify as interpretive within the meaning of the APA, must be adopted via notice-and-comment rulemaking in order to have an authoritative effect.

After *Allina,* improperly-adopted substantive rules, however they might be classified under APA analysis, would appear to have no ability to establish a rule different than or in addition to those which have been properly promulgated. Improperly-adopted substantive rules should have significance only to the extent that they have the "power to persuade" as support for the enforcement of properly-promulgated substantive rules.[189] By analogy to the APA, however, the deference doctrine could be applied to those classes of CMS rules explicitly excepted from notice-and-comment rulemaking under the APA. Because, after *Allina*, the government will not be able to access deference by arguing merely that a rule is interpretive; we would expect the focus of post-*Allina* disputes to be on whether rules are substantive or procedural. Under the Medicare Act, the analysis is binary: if the rule is substantive it must be adopted by notice and comment in order

187. *Allina*, 139 S. Ct. at 1811; *see also* Select Specialty Hosp.-Denver, Inc. v. Azar, 391 F.Supp.3d 53, 68 (D.D.C. 2019) (the Circuit's definition –which the Supreme Court thus neither fully endorsed nor rejected – grounded the definition of 'substantive legal standard" in the dictionary definition of "substantive law.").

188. *See generally Allina*, 139 S. Ct. at 1811–12.

189. *See* Kisor v. Wilkie, 139 S. Ct. 2400, 2414 (2019) (quoting *Christopher*, 567 U. S. at 159, quoting Skidmore v. Swift & Co., 323 U. S. 134, 140 (1944)) (agency guidance that is undeserving of deference is not authoritative and has only the power to persuade). We are unaware of any authority that advances a theory under which such guidance would be given weight in construing the meaning of a statute or regulation, beyond the power to persuade. *But cf.* Memorandum from Kelly M. Cleary, Deputy Gen. Counsel & CMS Chief Legal Officer, and Breanna E. Jenny, Deputy Gen. Counsel, Dep't of Health & Human Servs., to Demetrios Kouzoukas, Principal Deputy Admin. & Dir. of the Ctr. for Medicare, on Impact of *Allina* on Medicare Payment Rules (Oct. 31, 2019) [https://perma.cc/LPR3-BW3X] (which may be read to suggest that HHS subscribes to such a theory).

to be binding, and if it is not, it carries no inherent legal weight. The government is free to argue that a statute or regulation should be interpreted as it sees fit, but its argument carries no more weight than that advanced by the provider-defendant.[190]

B. The Medicare Act's Approach to CMS Sub-regulatory Guidance Is Best Understood in the Context of a Regulatory Scheme that Operates via Contractual Mechanisms

Allina's interpretation of the Medicare Act as requiring notice and comment for substantive rules to be enforceable means that, by statute, CMS is afforded less deference with respect to its interpretation of the rules that govern participation in federal healthcare programs than is afforded to other agencies with respect to their administrative schemes. While not widely or consistently recognized by the courts until the D.C. Circuit Court's decision in *Allina v. Price*,[191] the Medicare Act has long provided for a procedural approach to CMS rulemaking and guidance that is unique among federal agencies.[192]

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190. Indeed, this approach is supported by the regulations that CMS has promulgated under the Medicare Act. *See, e.g.,* 42 C.F.R. § 405.1062 (2019) (proscribing that ALJs, attorney adjudicators and the Medicare Appeals Council are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but are required to give substantial deference to these policies if they are applicable to a particular case).

191. *See supra*, note 12 and accompanying text.

192. In their brief to the Supreme Court, the Respondents explained the history of the Medicare statute's procedural requirements:

> When it first enacted the Medicare program in 1965, Congress gave the agency general authority to prescribe regulations for administering the program [but] did not specify at that time whether those regulations required notice-and-comment rulemaking . . . . In 1971, the agency announced a policy of following the APA's notice-and-comment procedures for rules relating to Medicare benefits . . . even 'where not required by law.' . . . In 1986, Congress mandated for the first time that the agency follow notice-and-comment procedures, and articulated some requirements different from those under the APA . . . . A year later, still concerned that 'important policies [were] being developed without benefit of the public notice-and-comment period,' Congress further amended the Medicare statute to specify the kinds of policy changes that require adoption by regulation after notice-and-comment. Pursuant to those amendments, the statute now mandates: No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation [through notice-and

In order to understand the reason for such differential treatment of Medicare rules and regulations, it is important to contextualize enforcement of the Medicare rules with respect to healthcare providers and suppliers. Healthcare provided to beneficiaries of federal healthcare programs is, in essence, a federally-procured service.[193] Enforcement of the regulations and sub-regulatory guidance that govern the provisions of these services primarily manifests (at least in theory), therefore, not as enforcement of universally-applicable industry regulations (e.g., EPA emissions standards applicable to all factories), but as administrative prosecution of the terms of a contract between the government and individual persons and entities for the provision of healthcare items and services.[194] Indeed, it is squarely the primary province of the states,

> comment rulemaking] . . . . When it adopted that language in 1987, Congress went a step further to ensure advance notice of Medicare policy changes. When 'manual instructions, interpretative rules, statements of policy, and guidelines of general applicability' are not required to be promulgated by notice-and-comment, Congress nonetheless required them to be published on a list in the Federal Register . . . . In 2003, Congress further modified the Medicare Act, again insisting on notice-and-comment rulemaking in circumstances where the APA does not require it: If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously-published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation. At the same time, Congress addressed the retroactive application of substantive Medicare policy. It mandated that a 'substantive change' made in any of several forms of administrative issuances—whether in 'regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability'—'shall not be applied *** retroactively to items and services furnished before the effective date of the change,' except under circumstances not applicable here. It also provides that 'no action shall be taken against a provider of services or supplier with respect to non-compliance with such a substantive change.'
>
> Brief for Respondents Allina Health Services et al. at 3–4, Azar v. Allina Health Servs. 139 S. Ct. 1804 (2019) (No. 17-1484) (internal citations omitted).

193. *See* 42 U.S.C. § 1320a–7b(f) (2018) (defining "federal health care program" in part as "any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government").

194. *See, e.g.*, *Part C and Part D Enforcement Actions*, CMS.GOV (Feb. 28, 2020), https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDEnforcement Actions- [https://perma.cc/L67L-S4JV] ("CMS has the authority to take enforcement or contract actions when CMS determines that a Medicare Plan Sponsor either: substantially fails to comply with program

rather than the federal government, to regulate broader public health.[195] Federal regulation of healthcare services is, on the other hand, more or less tied to the expenditure of federal funds.[196] Restrictions placed on federal reimbursement for healthcare services must, therefore, balance sound policy-making that protects the integrity of federal healthcare programs and the fundamental need to ensure that healthcare providers, as third-party contractors, are fairly reimbursed for the items and services rendered to federal healthcare program beneficiaries.

If CMS's regulatory scheme is seen as operating primarily as the terms of a procurement contract between the government and private parties, articulating the conditions under which such private parties agree to provide items and services for the government's benefit, it is unsurprising that the agency should not be able to unilaterally amend the terms of the arrangement by adding terms and conditions without proper notice.[197] As the *Kaiser* court noted, *Auer* deference is rooted in part in the supposition that, where there is ambiguity, the agency knows best what is intended.[198] This approach is at loggerheads with the well-known principle of interpretation of contractual ambiguity, of "construction against the drafter"[199] and underscores the reason why the traditional approach to deference to agency interpretations might have been seen as unsuited to CMS guidance. The opportunity for comment can be seen as reflecting the recognition that, while CMS will not negotiate these amendments separately, equity and the need for

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and/or contract requirements, is carrying out its contract with CMS in a manner that is inconsistent with the efficient and effective administration of the Medicare Part C and Part D program requirements, or no longer substantially meets the applicable conditions of the Medicare Part C and D program.").

195. *See* Jacobson v. Massachusetts, 197 U.S. 11, 24–7 (1905).

196. *See generally* Katherine A. Lauer, Jason M. Ohta & Amy E. Hargreaves, *Violations of Payment/Participation Conditions as Predicates for False Claims*, AM. BAR ASS'N, Spring/Summer 2011 [https://perma.cc/F68X-JAMP] (explaining that many conditions of participation in federal health care programs relate to quality of care)

197. Indeed, the *Allina* Court suggests this rationale when it states: "Congress could have thought those benefits especially valuable when it comes to a program where even minor changes to the agency's approach can impact millions of people and billions of dollars in ways that are not always easy for regulators to anticipate." 139 S. Ct. at 1816.

198. Kisor v. Wilkie, 139 S. Ct. 2400, 2412 (2019) ("The agency that 'wrote the regulation' will often have direct insight into what that rule was intended to mean.").

199. *See, e.g.*, Badie v. Bank of Am., 67 Cal.App.4th 779, 801 (1998) ("[I]f the uncertainty is not removed by application of the other rules of interpretation, a contract must be interpreted most strongly against the party who prepared it. This last rule is applied with particular force in the case of adhesion contracts.").

judicious policymaking in relation to the vast healthcare enterprise requires some opportunity for input prior to changing the rules of the game.

C. What is a Substantive Rule?

As explained above, post-*Allina*, CMS will have an incentive to characterize its rules affecting payment as non-substantive, and therefore, exempt from notice-and-comment rulemaking requirements.[200] The *Allina* Court did not, however, render a definitive, replicable definition of the term "substantive."[201] The question of whether and to what extent a non-substantive rule can support an argument that a healthcare provider was or was not entitled to payment, merits some attention.

In *Allina*, the Court rejected the government's argument that "interpretive rules" are categorically excluded from the Act's definition of "substantive rules."[202] It is clear, then, that the meaning of the term "substantive" for purposes of the Medicare Act is different from the meaning accorded the same term in APA parlance, where it is often used as a synonym for legislative rules.[203] While *Allina* allows for the possibility of an as-yet unarticulated compelling argument to the contrary, *Allina* holds that a CMS-created formula that determines amounts due to providers that is not expressed in the statutes or regulations is substantive "gap-filler".[204] Several courts post-*Allina* have held that similar payment-determinative formulas are substantive for purposes of the Medicare Act.[205] It also seems clear from *Allina* and its progeny that sub-regulatory guidance that merely states how the agency will implement a law, without altering the legal standards expressed in the law, need not be readopted in order for the principles

200. *See supra*, note 110 and accompanying text.

201. The dissent in *Allina* explains: "The Court not only leaves the APA behind; it fails to substitute any reasonably clear alternative standard. How is the agency to determine whether a rule 'establishes or changes a substantive legal standard'? At one point, the Court refers to the hospitals' view that the statute applies to agency actions that 'creat[e] duties, rights and obligations,' as distinct from [agency actions] that specif[y] how those duties, rights, and obligations should be enforced. But it later declines to 'go so far as' to fully endorse that view." 139 S. Ct. at 1823 (Breyer, J., dissenting).

202. *Id.* As noted above, the APA excludes interpretative rules from the term "substantive" rules, and by reason of such exclusion, exempts these interpretive rules from notice-and-comment rulemaking, thereby creating the possibility that they be given effect via deference.

203. *See, e.g.*, David L. Franklin, *Legislative Rules, Nonlegislative Rules, and the Perils of the Short Cut*, 120 YALE L. J. 276 (2010).

204. *See Allina*, 139 S. Ct. at 1817.

205. *See supra*, note 135 and accompanying text.

that are articulated in both the law and the sub-regulatory guidance to have legal effect.[206]

Beyond these two parameters, the courts have begun the work of determining whether, and when, CMS can apply standards that were not subjected to notice-and-comment to deny, withhold, or recoup payment for items or services rendered.[207] From these decisions, an analytical framework that juxtaposes substantive and procedural rights is emerging.[208] Under this framework, as a baseline inquiry, the court must consider whether the standard at issue is (i) procedural, or a mere policy statement, or (ii) substantive. If it is procedural or a policy, it is not subject to notice-and-comment, but is not binding, by definition.[209] If it is substantive, in order to have binding effect, and, indeed, any authority beyond the power to persuade, it must be adopted in a properly-adopted law or regulation.[210]

The substantive/procedural dichotomy was first articulated by the *Price* court, and reprised as a possible definition of the term in *Allina*, which held that the rule at issue in *Allina*:[211]

> establishes a "substantive legal standard." "Substantive law" is law that "creates, defines, and regulates the rights, duties, and powers of parties." BLACK'S LAW DICTIONARY (10th ed. 2014). A "substantive legal standard" at a minimum includes a standard that "creates, defines, and regulates the rights, duties, and powers of parties." That is precisely what HHS's 2012 Medicare fractions do. The fiscal intermediaries must use HHS's published Medicare fractions in determining how much the hospitals will be reimbursed. HHS's fractions therefore define the scope of hospitals' legal rights to payment for treating low-income patients.[212]

Policy statements similarly articulate organizing principles for agency operations and do not impose obligations or restrictions on providers. For example, in *Clarian Health West v. Hargan*, a pre-*Allina* case that interpreted and applied the Medicare Act in a manner similar to *Allina*, the D.C. Circuit addressed provisions of a Medicare Manual

206. *See supra* notes 168–170 and accompanying text.

207. *See infra*, notes 211–225 and accompanying text.

208. *See id.*

209. *See id.*

210. *See id.*

211. Allina Health Services. v. Price, 863 F.3d 937, 942-43 (D.C. Cir. 2017).

212. *Id.* Notably, the APA also contemplates and exempts from notice-and-comment requirements, separately from interpretive rules, a category of rules that are procedural, that comport with this dictionary definition: those rules that are of agency organization, procedure, or practice. *See supra*, note 136.

that related both to a change in the way in which the government provides hospitals extra reimbursement ("outlier payments") for extraordinarily expensive care, as well as agency enforcement priorities.[213] Consistent with *Allina* and our observation that standards that have the effect of determining the amount due are substantive, the *Clarian* court reasoned that changes to outlier payment calculations were substantive, as they clearly had an impact on the rights of healthcare providers who billed Medicare, explaining: "It cannot be seriously disputed that HHS's authority to reconcile outlier payments *alters providers' legal rights*. As [the application of the standard] may mean that a hospital receives millions of dollars less in payments than it otherwise would."[214] However, because this change in providers' rights was also expressed in statutes and regulations, and not just in the Manual, the standard had been properly adopted.[215] The remaining portion of the challenged standard appeared only in a Manual, but the court held that it was merely a policy that did not alter the applicable legal standards, [216] explaining:

> [T]he important point is that the agency maintains the same authority to reconcile any outlier payment that it had prior to the adoption of the Manual instructions. The instructions merely set forth an enforcement policy that determines when MACs will report hospitals for reconciliation. They do not change the legal standards that govern the hospitals, and they do not change the legal standards that govern the agency . . . . The agency's authority is accordingly exactly as it would be if the Manual instructions did not exist. The hospitals' legal entitlement to outlier payments is likewise unchanged. A hospital may pursue an action with the Board to challenge an agency decision to subject it to reconciliation without regard to . . . the . . . Manual instructions . . . . We conclude that the Manual instructions embody a general statement of policy, not a legislative rule, setting forth HHS's enforcement priorities. Policy statements do not establish binding norms. And they are not "rules" that must be issued through notice-and-comment rule making . . . . Nor are the instructions subject to the Medicare Act's independent notice-and-comment requirement because they do not establish or change a substantive legal standard.[217]

Because the substantive portions of the challenged standards were first articulated in properly-promulgated statutes and regulations and

213. Clarian Health West, LLC v. Hargan, 878 F.3d 346, 349 (D.C. Cir. 2017).

214. *Id.* at 355 (emphasis added).

215. *Id.*

216. *Id.* at 356–57.

217. *Id.* at 349, 355–56.

merely reprised in the Manual, and the remaining portions were merely statements of agency administrative policy without binding effect on the agency or the provider, both portions of the standards withstood challenge.[218]

Adding a little more clarity to the question of when a standard is procedural, in *Planned Parenthood of Wisconsin, Inc. v. Azar*, which construed the APA rather than the Medicare Act, the court explained:

> Although *Clarian Health* focused on distinguishing between a legislative rule and a policy (not procedural) rule, the factual similarities are instructive. Like the challenged policy in *Clarian Health*, the Announcement's revised scoring system (contested in the case at hand) imposes no legal obligations or prohibitions on the Plaintiffs, and is not outcome determinative: the Deputy Assistant Secretary retains final decision-making authority, just as before . . . . Indeed, the government has conclusively established that the Deputy Assistant Secretary makes the final award decisions and is not bound by panel scoring results . . . . Without legal effects that bind either the agency or private parties, the 2018 Announcement does not have ramifications that would require public participation and information-gathering "to safeguard the policies underlying the APA." . . . the 2018 Announcement is a procedural rule, lacking the force of law, and thus exempt from the APA's requirements for formal rulemaking.[219]

These cases stand for the proposition that a rule is substantive if it imposes a legal obligation or restriction on providers, or has an impact on a right to reimbursement in a manner that is not necessarily compelled by statute or regulation. A non-substantive rule, on the other hand, sets forth an agency's enforcement priorities, or organizing principles for the agency's operations. From this, we understand that, as so defined, "policy statements" and, for the same reasons, "procedural rules" are not substantive rules. Further, we understand that, by definition, neither policy statements nor procedural rules are binding on providers.

1. If a Documentation Requirement Creates a new Predicate to Meeting an Existing, Substantive Rule, Such a Requirement is, Itself, a Substantive Rule

In many cases, but-for program requirements (*i.e.*, requirements that create a unique predicate for payment) may masquerade as explanations of existing statutory or regulatory requirements. In such cases, a substantive, non-statutory norm may be expressed in a manner that makes it appear to be merely an administrative requirement In a

218. *Id.* at 357–59.

219. *Id.* at 307, 357–59.

post-*Allina* case, *Select Specialty Hospital-Denver, Inc. v. Azar*, the court held that the Medicare Act required CMS to afford full notice and comment to a standard that required that long-term care hospitals ("LTCHs") have received a notice of denial from Medicaid (referred to as "Remittance Advice" or "RA") before Medicare could be billed for the service.[220] While the court acknowledged that validly promulgated statutes and regulations precluded LTCHs from billing Medicare for Medicaid-covered services, the court concluded that the requirement was more than what was called for under such statutes and regulations.[221] As a result, the RA requirement was substantive and, per *Allina*, could only be enforced if adopted by notice-and-comment rulemaking.[222] The court explained that what sounded like a procedural requirement—that LTCHs obtain an RA from Medicaid indicating an absence of coverage—was in reality substantive because the RA could be obtained if the LTCHs enrolled in Medicaid. The court explained:

> As a result of CMS's implementation of [this] requirement, CMS changed not just the steps that existing LTCHs must take, vis-à-vis CMS, to be reimbursed, but also changed whether such entities must form contracts with third parties, the state Medicaid programs. Deeming CMS's imposition of this new obligation a mere change in procedure, as opposed to a change in substantive law, would be out of place. This new requirement of providing an RA, even if superficially appearing to be merely procedural, had significant substantive consequences for the contractual obligations that LTCHs had to undertake. The RA requirement has essentially changed the eligibility criteria for reimbursement under the Medicare Act for dual-eligible patients, by requiring

220. *Select Specialty Hosp.-Denver, Inc. v. Azar,* 391 F.Supp.3d 53, 70 (D.D.C. 2019), *reconsideration denied*, No. CV 10-1356 (BAH), 2019 WL 5697076 (D.D.C Nov. 4, 2019). Under long-standing Medicare regulations, the hospitals' bad debt was eligible for reimbursement, so long as, among other things, the provider is able to establish that "reasonable collection efforts were made." *Id.* at 57. CMS explained what constituted reasonable collection efforts in its Provider Reimbursement Manual ("PRM"). With respect to dual-eligible patients (i.e., those enrolled in both Medicare and Medicaid), the court explained that CMS required that, to meet this regulatory standard, the provider "must determine that no source other than the patient would be legally responsible for the patient's medical bill . . . Accordingly, the PRM requires providers to determine that Medicaid is not 'legally responsible' for a dual-eligible patient's medical bills before seeking reimbursement from Medicare", by billing Medicaid (the "must-bill" policy). *Id.* at 58. As evidence of compliance with this requirement, CMS required that the Providers obtain a Medicaid remittance advice ("RA"). *Id.*

221. *Id.* at 69–70.

222. *Id.* at 70.

> provider participation in the state Medicaid program. This change makes the RA requirement "substantive." . . .
>
> [T]he agency has not argued that these requirements are compelled by the Medicare Act itself. Rather, CMS is filling a 'gap' as to how best to administer the Medicare program. As the Supreme Court has made clear, however, CMS 'can't evade its notice-and-comment obligation under § 1395hh(a)(2),' just because the agency is changing a 'gap-filing policy.' Thus, when CMS imposed the RA requirement, it changed a "substantive legal standard"—state Medicaid participation—that the LTCHs had to satisfy for reimbursement to occur, and CMS was required to conduct notice-and-comment rulemaking . . . .[223]

Select Specialty Hospital-Denver, Inc. stands for the proposition that a requirement that compels a provider to enter into a contract with a third party is substantive, rather than procedural. The recognition that a requirement that mediates relationships between the provider and someone other than CMS is substantive and consistent with the holding in *Price* that a substantive rule is one that regulates the duties of the parties.[224] If a requirement imposes a mandatory directive relating to a provider's actions with respect to a party other than CMS, it should be considered to be substantive, rather than procedural. More importantly, *Select Specialty Hospital-Denver, Inc.* underscores the fact that when compliance with a documentation requirement compels a healthcare provider to engage in an act in which the provider would not be required to engage absent the documentation requirement, the documentation requirement is substantive, rather than merely procedural. This observation is critical, as many CMS-mandated actions manifest in the form of documentation requirements.[225] As illustrated by the two OIG Reports discussed above, the government has lately taken to suggesting that the mere failure to comply with a documentation requirement can be the basis of a repayment obligation under the reverse false claims provisions of the FCA, that is, that a claim submitted in the absence of the particular documentation constitutes a legally false claim.

The *Select Specialty Hospital-Denver, Inc.* holding should be read to encompass any documentation requirement that, in practice, requires

223. *Id.* at 69–70 (internal citations omitted).

224. *See supra*, note 10 and accompanying text.

225. *See, e.g.,* CTR. FOR MEDICARE & MEDICAID SERV., STANDARD ELEMENTS FOR DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS) ORDER, AND MASTER LIST OF DMEPOS ITEMS POTENTIALLY SUBJECT TO A FACE-TO-FACE ENCOUNTER AND WRITTEN ORDERS PRIOR TO DELIVERY AND, OR PRIOR AUTHORIZATION REQUIREMENTS (2020), https://www.cms.gov/files/document/se20007.pdf [https://perma.cc/7H2N-MZ64].

that a provider engage in acts in relation to a third party that are not otherwise required by law. Such an obligation alters the substantive rights of the provider and imposes, albeit indirectly, a new condition of participation. This same logic should apply when, in order to be able to comply with a documentation requirement, the provider must develop material operational capabilities. For example, a requirement that a hospital must document that it has a crash cart in every room in order for a particular service to be covered is, in actuality, a requirement that a hospital purchase crash carts. A requirement that a patient receive a particular test in order to qualify for coverage of a particular procedure is a requirement that the test be administered. It would seem, therefore, that both of these documentation requirements impose substantive obligations that are prerequisites to payment. To the extent that, in practice, a standard affects how the provider must engage with the world (*e.g.*, whether the provider must contract with a third party) or how the provider's engagement with the world is reimbursed (*e.g.*, how payments for accepting uninsured patients are calculated), such a rule impacts a right to payment and is, therefore, substantive. A rule that creates standards that only impact how a provider engages with CMS to satisfy other obligations (*e.g.*, meeting a filing deadline), on the other hand, could fairly be characterized a procedural.

It is clear from *Allina*, the Medicare Act, and the post-*Allina* case law that a CMS reimbursement standard is substantive if it: (i) changes the basis on which healthcare providers are compensated; (ii) imposes on a provider a duty to act or refrain from acting, that functions as a condition to payment; or (iii) otherwise mandates an action or process that is outcome-determinative of whether and how much payment will be made.

D. Only Substantive Standards that Are Properly Promulgated Can Serve as a Basis for FCA Liability

1. Non-Conformance with a Substantive Standard That is not Properly Adopted Cannot Serve as a Basis for a FCA Action Based on Legal Falsity

Allina sets forth a major boundary on the requirements on which CMS can condition payment.[226] While not itself an FCA case, *Allina* appears to have substantial implications for the universe of requirements to which a healthcare provider may be held to account via the FCA. If a substantive requirement does not satisfy the Medicare Act's requirement for substantive rulemaking, it cannot impact a right to payment; and if such a requirement cannot impact a right to payment, then the requirement cannot be material to payment under an *Escobar* analysis because CMS cannot assert that it may not or

226. *See supra*, notes 179–198 and accompanying text.

would not have paid the claim but for its belief that the requirement had been met. Put simply, the theory of legal falsity falls apart if CMS lacked authority to withhold payment for non-compliance with the requirement at issue.

Recently, a district court addressed an FCA claim predicated on non-conformance with a standard that appeared in a Manual.[227] The district court dismissed the claim because the sub-regulatory standard with which the defendant had allegedly not complied imposed additional substantive requirements.[228] The court first concluded that the requirement (referred to as "the 24-hour policy") was a "substantive legal standard" and consequently, required notice-and-comment rulemaking procedures, because, like the standards at issue in *Allina* and *Select Specialty*, the standard "determined entitlement to reimbursement . . . delineat[ing] the circumstances in which a hospital is entitled to higher inpatient reimbursement."[229] The court went on to

227. Polansky v. Exec. Health Res., Inc., 422 F. Supp. 3d 916, 937 (E.D. Pa. 2019).

228. *Id.* at 938.

229. *Id.* at 935. The court explained:

> Case law applying the District of Columbia Circuit's formulation of the definition for "substantive legal standard" illuminates a distinction between, on the one hand, rules that determine reimbursement and, on the other, statements that set forth enforcement policies. If a policy affects the right to, or amount of, reimbursement, it is more likely to be deemed a "substantive legal standard" . . . . Conversely, if a policy does not affect the authority of CMS, but simply provides instructions for enforcement, it is more likely not to be characterized as a "substantive legal standard." Three cases—all applying the Circuit's definition of "substantive legal standard"—explore the contours of this distinction. Two of these cases found that, because the policies at issue affected the applicable reimbursement regime, the policies were "substantive legal standards" under the Medicare Act. In the District of Columbia Circuit's Allina opinion, the Circuit held that the Medicare payment fractions at issue were "substantive legal standards" under its definition, because the formulae "determine[ed] how much the hospitals [would] be reimbursed." *Allina*, 863 F.3d at 943. Similarly, in Select Specialty, a district court for the District of Columbia applied the Circuit's definition of "substantive legal standard" to a CMS policy (the "must-bill" policy) that required hospitals to bill state Medicaid before seeking federal reimbursement. 391 F. Supp. 3d at 61. Select Specialty concluded that the must-bill policy was a "substantive legal standard" because it "essentially changed the eligibility criteria for reimbursement under the Medicare Act." *Id.* at 69. The last of the cases applying the Circuit's definition found that the policy at issue, which merely provided instructions to direct enforcement, was not a "substantive legal standard" under the Medicare Act. In *Clarian Health West, LLC v. Hargan*, 878

reject the relator's argument that the 24-hour policy was merely an interpretation of the prior standard and held that it was, rather, a "gap-filler" which was, by reason of *Allina* explicitly, subject to notice-and-comment obligations.[230] The court held, apparently without seeing the need for any further analytical justification, that the:

> Relator cannot justify CMS's failure to provide notice-and-comment for the 24-hour policy by characterizing it as mere guidance on a preexisting standard when the policy, in substance, is a gap-filling exercise prompted by the ambiguity of the prior policy. . . . Since the 24-hour policy was contained in agency manuals that had not been promulgated pursuant to notice-and-comment, *Allina* compels the conclusion that there can be no FCA liability on Relator's . . . claims.[231]

This case reinforces and applies some of the principles originating in the earlier cases bearing on the meaning of *Allina*, as well as demonstrates, albeit in a rather conclusory manner, that a rule that is substantive, but not properly adopted, cannot serve as a basis for bringing an FCA claim based on legal falsity. This is because the theory of legal falsity posits that it is a fraud on the government to request payment for an item or service with undisclosed knowledge of circumstances that would cause the government to refuse payment of the claim.[232] If an FCA case is predicted on a theory of legal falsity it must, therefore, allege non-conformance with binding law.[233]

> F.3d 346 (D.C.C. 2017), the Circuit applied its definition to a policy expressed in a manual that provided criteria to guide healthcare insurers in selecting hospitals for reimbursement reconciliation. Clarian found that this policy was not a "substantive legal standard" because it "merely set forth an enforcement policy that determines when [private healthcare insurers] will report hospitals for reconciliation [to adjust reimbursement received]." *Id.* at 378–79. According to the Clarian court, in finding that the policy was not a substantive legal standard, the "important point [was] that the agency maintain[ed] the same authority . . . that it had prior to the adoption of the Manual instructions." *Id.* at 378.

Id. at 934–35.

230. *Id.* at 936.

231. *Id.*

232. *See supra*, notes 6–9 and accompanying text.

233. A claim is legally false when the claimant has falsely certified, either impliedly or explicitly, that, in the process of delivering the item or service for which reimbursement is claimed, she complied with a *statute or regulation* that is a "material condition of payment." *See supra*, note 48, note 41, and accompanying text; *see also* Franklin, *supra* note 203, at 279 (arguing in the context of the APA that: "rather than asking whether a

Substantive requirements that are not properly adopted are not binding, nor, as we discuss below, can they be material.

2. Deviation from Procedural Standards Cannot Serve as a Basis for FCA Liability

As discussed above, procedural requirements, by definition, do not create binding obligations on providers, but rather mediate the procedural aspects of the relationship between the agency and the provider.[234] As they are not obligations that must be fulfilled in order to deserve payment, they cannot serve as a predicate for a FCA action based on legal falsity. Relatedly, it is difficult to imagine how non-conformance with a procedural requirement could be materially misleading to the government, in the sense that the term is used in *Escobar*; which is to say with the non-compliance going to the essence of the bargain.[235] Using the *Ruckh* court's interpretation of what *Escobar* requires in this regard, in order for non-conformance to be material, it must result in "a material deviation in the value received."[236] Under this standard, procedural deviations that do not affect the value of what was received would not be material, and it is difficult to imagine a purely procedural requirement that is, and perhaps logically impossible for a purely procedural requirement to be, determinative of the value of the item or service for which reimbursement is claimed. Finally, as procedural rules are defined as involving interactions between the government and the provider, non-compliance will generally be evident to the government prior to payment, and payment in the face of evident non-compliance would mitigate against considering the rule material. It would, moreover, be difficult to argue that a defect in a claim that was readily apparent to government actors responsible for paying the claim nonetheless rendered the claim a fraud. It would seem that, by definition, when the government pays a claim despite full knowledge of an open and unconcealed procedural defect, the procedural defect neither renders the claim a legal falsity nor materially deficient. For all of these reasons,

challenged rule was designed to be legally binding in order to determine whether it must undergo notice and comment, courts should simply turn the question inside-out and ask whether the rule has undergone notice and comment in order to determine whether it can be made legally binding. Rules that have been through notice and comment would be accorded the force of law in later enforcement actions; rules that have not been through notice and comment would be denied such force. No longer would a rule's substantive nature dictate its procedural provenance; instead, its procedural provenance would determine its substantive effect.").

234. *See supra* Section III.C.

235. *See supra*, note 136 and accompanying text.

236. United States v. Salus Rehab., LLC, 304 F. Supp.3d 1258, 1263 (M.D. Fla. 2018).

and others, it would seem that most, if not all, procedural requirements will be evidently minor or insubstantial.

3. A Coherent Limitation on Predicates to FCA Liability

When viewed in the context of the FCA, *Allina* creates a coherent gatekeeping mechanism that may serve to weed out the most unfair and unpredictable of FCA claims: those predicated on CMS's rapidly changing sub-regulatory requirements and informal preferences. If only properly-adopted substantive standards can serve as a predicate for an FCA action, and the standard in question has not been adopted through notice-and-comment rulemaking, the case simply cannot proceed.

Limiting FCA violations based on legal falsity to violations of substantive standards adopted via notice-and-comment rulemaking is rational and equitable. Without such a limitation, as evidenced by the inconsistent and convoluted body of FCA case law discussed in Section III of this piece, healthcare providers would be subject to the very real risk that they will not only be refused payment for items and services that were, indeed, rendered, but will also be subject to substantial (and often ruinous) penalties for violations of any number of sub-regulatory requirements the import of which they did not or could not grasp. In light of the failure of the FCA's scienter standard to provide a meaningful limitation on FCA liability, it is appropriate, if not necessary, for the universe of requirements that may serve as predicates to FCA liability to be limited to those that have been subject to notice and comment, providing fair warning to healthcare providers that compliance may be a necessary condition of reimbursement.

This approach does not define which requirements are, indeed, material under *Escobar*, but it does dovetail with the approach taken by courts that have construed *Escobar's* materiality standard, concentrating on the issue of whether the non-conformance went to the "essence of the bargain."[237] Procedural missteps do not affect the value of the item or service rendered, while some, but not all, violations of substantive requirements could.[238] Acknowledging that the FCA is a

237. *See* Universal Health Servs. Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 2003 n.5 (2016).

238. This does not mean that non-compliance with a procedural rule could not have an effect on payment. A provider could, subject to appeal rights, be denied payment ultimately because of non-conformance with a purely procedural standard, such as missing a filing deadline for a cost report. However, a provider could not be prosecuted for an FCA violation on that basis. For example, non-compliance with standards that require that a provider maintain or submit particular documentation as proof of medical necessity (a statutory requirement) are either substantive, in which case they must be adopted by notice-and-comment rulemaking, or procedural, in which case, so long as non-compliance does not affect the value of the services provided, non-compliance with these standards cannot be a basis for an FCA action. The government could, however, in the absence of

statute that seeks to protect the government from being defrauded, it should be applied only when the government has, in fact, been tricked into paying for items and services that are not as valuable as represented.[239] Having established non-conformance with a substantive, binding rule, it will still be necessary to establish that the non-conformance was material.[240] Engaging in the first inquiry will, however, vastly narrow the field of rules to which the materiality screen will have to be applied.

IV. APPLYING *ALLINA* AND *ESCOBAR* TO FCA CASES

Taken together, *Allina* and *Escobar* create a three-step process for analyzing whether a violation of a given CMS requirement renders a claim false for the purposes of the FCA. In bringing an FCA case, post-*Escobar* and post-*Allina*, the government is required to demonstrate that the defendant has violated a legally-binding, material condition of payment. Whether a law is binding and material are distinct threshold issues that should be analyzed in terms of whether the moving party has succeeded in stating a claim; that is, to determine: 1) if there is actually a law that is asserted to have been violated which is of a type with which non-compliance could render a claim false, and 2) whether the law was actually applied by the government as a material condition of payment. Once it is established that a defendant can be held to account under the FCA for non-compliance with a given requirement, courts must then ask whether the defendant knew, or should have known, that she had failed to comply with a requirement that was material to the government's decision to pay a claim.

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such documentation, challenge the medical necessity of the claimed item or service, and, if the provider could be shown to have provided medically unnecessary services, such non-conformance with the law could serve as a predicate for FCA liability.

239. Or, as is the case when the violation is predicated on a violation of the anti-kickback statute, are provided in a manner that is specifically called out as constituting a FCA violation under 42 U.S.C. § 1320a-7b(b)(g).

240. The materiality screen can also be used to answer the question of whether, and when, FCA liability can be predicated on non-conformance with the regulatory requirements of agencies other than CMS. It would seem that there is less likelihood that these requirements would be material to a CMS decision to pay than would be its own requirements. This approach would go a long way to resolving the odd dynamic created by *Allina*, which would allow the use of non-CMS sub-regulatory guidance, at least so far as the same constituted interpretive rules and, was thus, accorded deference, but not CMS sub-regulatory guidance, as a predicate for an FCA case.

A. STEP 1: The Standard from which the Defendant is Alleged to Have Deviated, Must be Expressed in Binding Law

Allina holds that a CMS requirement that is substantive must be properly adopted in accordance with the procedural requirements of the Medicare Act.[241] Under *Allina*, a substantive requirement cannot be read into a statute or regulation as a gap-filler and given legal import via judicial deference to define the substance of the statutory or regulatory requirement.[242] A substantive requirement that is not properly adopted carries no authority beyond the power to persuade (and, certainly is not binding), and, thus, legal falsity cannot be predicated on non-conformance with such a requirement.[243]

After *Allina*, it is relatively easy to identify those CMS requirements that are binding, as they must be set forth in properly-adopted statutes, regulations, or NCDs.[244] Under *Allina*, CMS sub-regulatory guidance, such as that expressed in a Manual, an LCD, or in another contractor publication, simply cannot be used to create a substantive requirement that is not evident in properly-promulgated law.[245] This is not to say that sub-regulatory guidance is without probative value. Requirements that do not receive full notice and comment simply lack value in establishing the substance of a standard against which non-conformance can be measured. Such a requirement may be probative under STEPS 2 and 3 below, by lending insight into whether the government considers a condition of payment, as promulgated, to be material to payment, or as evidence that the defendant likely knew the requirement to be material. A requirement that is not a binding substantive requirement, under *Allina*, may not, however be used to define the contours of the requirement itself.[246] Take, for example, a hypothetical regulatory requirement that states that a physician's signature must be obtained within a "reasonable" time after admission to a skilled nursing facility. Assume further that CMS has issued four transmittals and conducted seven trainings within the last year, each stating that payment will be denied if a signature has not been obtained within 72 hours. CMS's sub-regulatory statements are not relevant to a determination of whether a skilled nursing facility that often obtains physician signature at 75 or even 100 hours after admission has violated a condition of payment. Such statements are, however, highly probative with respect to the question of whether the government considers the underlying requirement – that a physician's

241. *See supra,* Section III.D.

242. *Id.*

243. *Id.*

244. *Id.*

245. *Id.*

246. *Id.*

signature be obtained without undue delay – to be material to its decision of whether or not to pay a claim (STEP 2). As well, such statements may have a role in proving scienter (STEP 3).

B. STEP 2: The Requirement Imposed by the Law Must be Material

Under *Escobar*, the requirement must be one: (i) on which payment may, in fact, be conditioned,[247] (ii) that is by nature material,[248] and (iii) that in practice, is applied as a condition of payment by CMS.[249] This means that, in addition to being a binding law (see STEP 1), the standard must be both material and demonstrably material to the government's decision to pay. Not all rules that are adopted by notice-and-comment rulemaking will be material, however, as some may be procedural. Thus, while evidence related to promulgation of the requirement (e.g., statements made in notices of proposed rulemaking) may be highly relevant to a determination of materiality, materiality is a distinct requirement that must be shown independent of a showing that the rule at issue is validly promulgated under the Medicare Act.

C. STEP 3: The Defendant Must Know that the Requirement is Material to the Government

The defendant must have the requisite scienter: she must know (or should know) that the requirement is material to the government's decision to pay. Concluding that a requirement is material and authoritative, and is treated as such by the government is, therefore, necessary, but not sufficient, to find that failure to meet such a requirement could render a claim false.

As a practical matter, because of the relative paucity and clarity of properly-adopted statutes and regulations, and the narrow scope of subject matter that NCDs may address, as compared to the volume and scope of sub-regulatory guidance, excluding standards that are not properly adopted as a basis for FCA liability predicated on legal falsity should have the practical effect of filtering out many immaterial terms (i.e., all of those that are purely procedural or insignificant enough not to merit formal rulemaking) and substantially reducing the guesswork related to establishing materiality.

CONCLUSION

In *Escobar*, the Supreme Court attempted to impose a reasonable constraint on the types of non-compliance that could serve as a

247. For example, a requirement that was articulated optional, but not determinative of eligibility, could not be material.

248. The *Escobar* Court held that materiality cannot be found where non-compliance is minor or insubstantial. Universal Health Servs. Inc. v. United States *ex rel.* Escobar, 136 S. Ct. 1989, 2002-04 (2016).

249. *Id.* at 2003.

predicate for a FCA claim based on legal falsity.[250] It held that in order for a healthcare provider to be subjected to the FCA's harsh penalties under a legal falsity theory, she would have to have flaunted a requirement that was not a mere technicality, but, rather, one that was material to the government's decision to pay the relevant claim. Owing in the main to the overwhelming volume and diversity of types of CMS regulatory and sub-regulatory guidance as well as the fact that the materiality test involves the exceptionally difficult task of assessing the subjective state-of-mind of the government, subsequent cases seeking to apply *Escobar's* holding demonstrate that this requirement fails to create predictability and consistency. When coupled with the holding in *Allina*, however, it gains utility. *Allina* fundamentally alters the FCA landscape by articulating an objective test for determining which governmental statements have sufficient legal import to have binding legal effect; thereby not only narrowing the universe of potentially material standards, but also ensuring that the government has signaled its view of the materiality of the standard in a way calculated to give notice both of the standard and of its position that the standard is material. Read together, the holdings in these cases promote equitable, predictable, and consistent enforcement of CMS requirements by ensuring that the FCA is employed to enforce only those requirements that have been objectively demonstrated to be of sufficient importance to merit formal adoption.

250. *See id.* at 8.