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Medicare Enrollment Defenses: Regs, Forms, and the Supreme Court

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Introduction

Medicare's enrollment system – the system by which practitioners and health care entities obtain Medicare billing credentials – is the central mechanism by which CMS controls provider access to the Medicare Trust Fund. It is, in other words, the very definition of "gatekeeping." Over time, the process to obtain billing credentials from Medicare has grown more and more cumbersome and intrusive. As the process has become more complex, requiring both more information and more frequent submission and maintenance of such information, it has introduced false claims liability risk for health care practitioners and entities if they fail to properly enroll and to maintain their enrollment. This article explores the history of Medicare's enrollment system and how it has developed over time. It examines the current regulatory landscape and how regulations interplay with Medicare's manual provisions. It further examines how attorneys may advise clients grappling with Medicare enrollment issues, both in a practical sense, and in a legal one. The article delves into Supreme Court caselaw to discuss possible defenses (and their potential rebuttals). Finally, it explores certain problems that health care practitioners may face in their ongoing obligations relating to Medicare enrollment, and attempts to apply guidance notions discussed in the article, through the examination of real world scenarios.

1.0 Enrollment History

In the earliest days of the Medicare system, there was no true centralized enrollment system.[1] Instead, individual Medicare carriers and fiscal intermediaries ("FIs")[2] had their own idiosyncratic enrollment forms. In 1986, however, the Health Care Finance Administration ("HCFA") [3] issued a new two-page form consisting of eighteen questions: the HCFA-1513. These questions asked for information regarding who owned the business, mailing addresses, and other similar demographic information. The form was to be filed at the state level, either with a state agency, or the HCFA regional office.

In 1996, HCFA issued the HCFA-855, a new form to be implemented beginning the following year. Two pages bloomed into sixteen, and now the form had to be filed with HCFA itself or a carrier or FI. At this same time, HCFA also issued the HCFA-855R to allow health care practitioners to reassign their right to payment, and the HCFA-855C to allow for the submission of changes to enrollment information, instead of filling out a complete new HCFA-855. At this time, Bruce Vladek, the administrator of HCFA explained in congressional testimony that the goal of the new enrollment process was to "clarify the provider enrollment process, and strengthen HCFA's ability to combat fraud and abuse by not allowing 'bad actors' to become Medicare providers or suppliers."[4] In other words, the formalized enrollment process was purpose-built as an effort to combat fraud within Medicare. In relatively short order, HCFA added the HCFA-855R to allow for individual reassignment of the right to payment to another entity (e.g., an employer), and the HCFA-855C, used to submit changes to enrollment information.

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[1] For a more fulsome history of the early portion of Medicare's enrollment process, see Shay, Daniel, "Enrollment in Medicare: Fraternity Hazing or Keeping Out Bad Actors?", Health Law Handbook, Thompson Reuters pub., 2009 ed., pp. 1-34.

[2] The precursor entities to today's Medicare Administrative Contractors ("MACs").

[3] The precursor entity to today's Centers for Medicare and Medicaid Services ("CMS").

[4] 1996 CONG US HR 1770.

1.1 2001 to 2009

In 2001, HCFA split the HCFA-855 into two separate forms: "providers" would now use the HCFA-855A; "suppliers" would use the HCFA-855B. The term "providers" includes various institutional health care entities, such as hospitals, critical access hospitals, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, and others. By contrast, "supplier" is defined to mean "a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare."[5] Thus, "providers" would fill out the HCFA-855A to be allowed to be paid under Medicare Part-A, while "suppliers" would complete the HCFA-855B to be paid under Medicare Part-B. The new 855B and 855A made additional changes, such as streamlining the reporting of owners and managers; in previous versions of the forms, this information was reported on separate pages, but the information could now be reported on a single, consolidated page. The concept of the "delegated official" also appeared on the forms for the first time with the 2001 changes, while the HCFA-855C was retired; changes to enrollment information would now be made on the 855A and B forms themselves.

The next major round of changes occurred in 2006. By this point, HCFA had become CMS, and so the names of the forms changed to CMS-855A, CMS-855B, and so forth. The 2006 reforms saw the implementation of the "revalidation" concept: the process by which providers and suppliers are periodically required to submit a complete, up-to-date enrollment application even after having been provided with Medicare billing privileges. A proposed version of revalidation published in 2003 would have required that revalidations occur every three years[6], but this was changed to every five years in the final rule three years later.[7]

One of the more significant changes, and one which still resonates to this day, was the change in retrospective billing (sometimes referred to as "back billing"). Prior to 2009, CMS itself described how the process worked as follows: "…If a supplier is enrolled in the Medicare program in December 2008, with an approval date back to October 2006, that supplier could retrospectively bill for services furnished to Medicare beneficiaries as early as October 1, 2006."[8] In other words, a provider or supplier could, in essence, reach back as far as it wanted for retrospective billing, as long as it complied with the requirements of the Medicare system at the time. In practice, this relied on a kind of "honor system" whereby providers and suppliers were claiming that they met Medicare's requirements by virtue of submitting claims for services stretching back into history, but all CMS had to go on was the provider's or supplier's word. Nevertheless, the system remained in place for many years, and when asked about perceived changes to effective billing dates, CMS stated in 2006, "It was never our intent to change our policy on effective billing dates…We will continue to pay claims under all current reimbursement policies."[9]

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[5] The definitions for "provider" and "supplier" can both be found at 42 CFR § 400.202.

[6] See, 68 Fed. Reg. 22064 (April 25, 2003).

[7] See, 71 Fed. Reg. 20754 (April 21, 2006). "Off-cycle" revalidations are still permitted, however. See, 42 CFR § 424.515(e).

[8] 75 Fed. Reg. 37535 (November 19, 2008).

[9] 71 Fed. Reg. 20763 (April 21, 2006).

However, a mere three years later, CMS changed fundamentally the rules to drastically shrink the window for retrospective billing. Under the then-new 2009 rule, a provider or supplier would now receive an "effective date of billing privileges," which itself would be defined as the *later* of: (1) the date on which the provider or supplier submitted an enrollment application that could be successfully processed, or (2) the date on which the supplier or provider first started rendering services at the location being enrolled.[10] Retrospective billing would be limited to only up to 30 days prior to the effective date of billing privileges.[11]

As an explanation for the somewhat abrupt about-face, CMS explained, "We maintain that it is not possible to verify that a supplier has met all of Medicare's enrollment requirements prior to submitting an enrollment application."[12] In addition, the availability of the Provider Enrollment, Chain, and Ownership System ("PECOS"), Medicare's then-new online enrollment system, was expected to decrease the need for Medicare contractors to request additional information in instances of incomplete applications, thereby speeding up processing times overall, and reducing the need for retrospective billing beyond the 30-day limit.[13]

1.2 2010 and Increased Scrutiny

The passage of the Patient Protection and Affordable Care Act of 2010 ("ACA")[14] resulted in seismic changes across the health care landscape, and Medicare enrollment was no exception. Under the ACA, CMS was now required to create a new screening process that would run criminal background checks, run cross-state licensure checks, perform fingerprinting, as well as perform other screening efforts.[15] In addition, providers and suppliers were required to disclose "uncollected debt," meaning Medicare, Medicaid, or CHIP overpayments for which CMS or the state had sent notice to the supplier, as well as any civil money penalties imposed under the Medicare program.[16]

Suppliers could now be categorized at different risk levels, with those risk levels being adjusted by CMS from time to time. The new risk categories included Limited Categorical Risk for physicians and non-physician practitioners, medical clinics, group practices, ASCs, end-stage renal disease facilities, and home infusion therapy suppliers. Health care entities at the Limited Categorical Risk level are subject to verification of licensure, verification of meeting applicable federal and state regulations, and certain

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[10] 42 CFR § 424.520(d)(1)

[11] 42 CFR § 424.521(a)(1).

[12] 73 Fed. Reg. 69767 (November 19, 2008).

[13] See, 73 Fed. Reg. 69769 (November 19, 2008).

[14] P.L. 111-148.

[15] 42 U.S.C.A. § 1395hh(j)(2).

[16] The new requirements were eventually published as regulations at 76 Fed. Reg. 5862 (February 2, 2011). See also, 42 CFR § 424.519(a)-(b); 42 CFR § 424.502 for the definition of a "disclosable event," which itself includes uncollected debt.

database checks.[17] At the Moderate Categorical Risk level are ambulance suppliers, community mental health centers, comprehensive outpatient rehabilitation facilities, hospices, independent diagnostic testing facilities ("IDTFs"), and independent clinical laboratories, as well as physical therapists enrolling as individuals or group practices, x-ray suppliers, and others. In addition to the scrutiny faced by the Limited Categorical Risk entities, those in the Moderate Categorical Risk group are subjected to on-site visits.[18] The High Categorical Risk group includes durable medical equipment, prosthetics, and orthotics suppliers ("DMEPOS"), home health agencies, skilled nursing facilities, newly-enrolling hospices, and others. These entities are subjected to the same scrutiny as the two lower levels, plus they must submit fingerprint sets for all 5% or higher direct or indirect owners, for background checks including FBI criminal history checks.[19] The categories have also changed over time, with some types of providers and/or suppliers being shifted to higher categories.[20] For example, when first published, the final rule categorized skilled nursing facilities ("SNFs") in the lower categorical risk group.[21] As of this writing, however, newly enrolling SNFs are categorized in the high categorical risk group, while some revalidating SNFs fall within the moderate categorical risk group.[22]

In addition to the screening authority, CMS was also empowered to impose six-month moratoria by provider types, in the event that CMS identified data trends that indicate a high risk of waste, fraud, or abuse. Moratoria can also be imposed if a state has done so, either by geographic area or by provider type (or both); and CMS can, in consultation with the Department of Justice ("DOJ") or the Department of Health and Human Services ("HHS") Office of Inspector General ("OIG") identifies a provider or supplier type or geographic area has having significant potential for waste, fraud, and abuse.[23] At present, there are no moratoria in effect.[24] However, CMS has previously placed moratoria on home health agencies, and ground ambulance suppliers.[25]

1.3 Enrollment Form Changes

[17] 42 CFR § 424.518(a).

[18] 42 CFR § 424.518(b).

[19] 42 CFR § 424.518(c).

[20] To date, no provider or supplier types have been moved to lower risk categories, however.

[21] See, 76 Fed. Reg. (February 2, 2011).

[22] 42 CFR §§ 424.518(b)(1)(ix) for revalidating SNFs, 424.518(c)(v) for newly enrolling SNFs

[23] 42 CFR § 424.570.

[24] See, https://www.cms.gov/medicare/enrollment-renewal/providers-suppliers/chain-ownership-system-pecos/provider-enrollment-moratoria. Although this website was last updated September 10, 2024, no new moratoria have been announced.

[25] See, https://www.cms.gov/newsroom/press-releases/cms-imposes-first-affordable-care-act-enrollment-moratoria-combat-fraud.

The enrollment forms themselves have also undergone many changes over the years, the full range of which is beyond the scope of this article.[26] Over time, the wording of certain sections of various forms has been revised, forms have been reorganized, and other changes have occurred within them. Forms have also been added over time, while others were later discontinued. For example, the CMS-855O form was introduced in 2011.[27] This form is most often used by suppliers who have opted out of Medicare, and no longer act as either participating or non-participating suppliers; instead, they are wholly outside the Medicare system and enter into private contracts with patients under which the supplier may charge the patient whatever they wish, without being limited by Medicare's limiting charge or the Medicare Physician Fee Schedule. Even a supplier who has opted out of Medicare can still order services for Medicare beneficiaries and make referrals to other participating suppliers. Identifying information about the referring or ordering practitioner is captured on the CMS-1500 claims form. Yet, prior to 2011, CMS would have had no record whatsoever of an opted-out physician. Thus, if their NPI appeared on a claim as the ordering or referring physician, CMS would have had no knowledge of this individual. When the ACA was passed, it mandated the creation of the form, prompting CMS to issue the CMS-855O, which would now capture the information of suppliers who are not enrolled as billing providers, thereby allowing CMS to recognize ordering and referring physicians even if they did not participate in Medicare.[28]

Similarly, the CMS-855R was discontinued in 2023, and the information reported on the form was incorporated into the CMS-855I[29] form as simply a separate section of the CMS-855I. However, not all forms are updated at the same time. As of this writing, the CMS-855B still includes a requirement within it to submit CMS-855R forms for each enrolling individual who is reassigning their right to payment to the group, even though the CMS-855R no longer exists. Unless and until the CMS-855B is updated, this language will remain as a "requirement," even though such requirement is now impossible to meet.

The main benefit of understanding the history of Medicare enrollment is certainly not the academic joy of delving into government forms. A good grounding in the history can assist attorneys when representing clients facing problems with their Medicare enrollment, some of which may arise because of conflicts, such as the "requirement" of the CMS-855B to submit a now-discontinued CMS-855R, instead of referencing the CMS-855I. The forms exist alongside the requirements of the Medicare regulations, and the instructions of the CMS Medicare manuals.

2.0 Advising Clients on Medicare Enrollment Matters

[26] For additional information on the history of Medicare enrollment and the forms used, see Shay, Daniel, "Enrollment in Medicare: Fraternity Hazing or Keeping Out Bad Actors?", Health Law Handbook, Thompson Reuters pub., 2009 ed., pp. 1-34; Shay, Daniel, "'Halt! Who Goes There?' – Coping with the Continuing Crackdown on Medicare Enrollment," Health Law Handbook, Thompson Reuters pub., 2011 ed., pp. 71-102; Shay, Daniel, "The Medicare Part-B Enrollment Obstacle Course: It Hasn't Gotten Any Easier," Health Law Handbook, Thompson Reuters pub., 2019 ed., pp. 303-335.

[27] See, https://omb.report/icr/201105-0938-013.

[28] The provision of the ACA requiring such enrollment was § 6405.

[29] The form used by individual practitioners to enroll in Medicare.

Understanding Medicare's rules for purposes of client advice often requires adopting two distinct mindsets. The first is to offer general advice, explaining what the current state of the rules is in practical terms. The second is to help craft a legal defense. Depending on the client's goals, guidance with respect to Medicare enrollment requirements may vary.

2.1 The General Advice Approach

The old saying "The best defense is a good offense" is inaccurate; the best defense is not needing a defense in the first place. Towards this end, much of client representation in the Medicare enrollment arena is oriented around minimizing the need for a legal defense. Under this approach, the hierarchy of documents, and parsing which are legally binding and which are merely general statements of the regulators' thinking that do not impose legal requirements, is less of a consideration. Instead, the focus is to understand the rules, and then follow them. The goal in this case is usually to present the smoothest path forward for the client in practical terms, so that it may submit claims to Medicare, be paid for those claims, and otherwise generally be left alone by Medicare.

Under the "general advice" approach, the regulations are merely a starting point, and other language may be illustrative and offer guidance that can provide the client a path forward free from pitfalls. Regulatory commentary, manual language, and the precise language of the forms are helpful tools in divining the requirements that will satisfy the CMS and the MAC. Thus, advice is less about what is legally defensible, and is more about a clear understanding of what the process of obtaining and maintaining Medicare billing privileges requires, as guided by the regulations, the manuals, and the forms.

2.2 The Legal Defense Approach

Under this approach, the goal is to minimize the client's legal exposure and, when necessary, craft an actual defense in response to federal inquiries or false claims allegations. Within the Medicare enrollment context, the primary source of legal exposure will come from False Claims Act liability, most likely resulting from relators bringing suit against a Medicare supplier like a physician group. The following arguments are presented as potential defenses to such suits. They are offered for two reasons: first, in the unfortunate case that a client's circumstances require it; second, to help expand how attorneys think about these issues, even if they primarily offer general advice to their clients. This approach relies upon two Supreme Court cases, discussed more fully below.

2.3 *Allina* in the Defense Context

In the first Supreme Court case, *Azar v. Allina Health Services*,[30] the Court addressed a dispute over the applicable payment rate for hospitals, and whether that rate properly included Medicare Advantage patients or excluded them. If the Medicare Advantage patients were included, the hospitals' payment rate would be lower; if they were excluded, the rate would be higher. Without providing an exhaustive history of the matter,[31] CMS had vacillated on how the rate was calculated, publishing and then withdrawing regulations pertaining to the rate at various points. However, for a period in 2012,

[30] 587 U.S. 566 (2019).

[31] A more detailed history of the payment rate in question can be found in *Allina*, at 570-572.

CMS did not issue regulations at all, and instead published manual provisions to establish the rate, relying upon the manual language as the basis for including Medicare Advantage patients in the calculus. In response, the hospitals filed suit, challenging the use of the manual provisions.

While federal regulations are often governed by the Administrative Procedures Act ("APA"), the case was instead analyzed under the Medicare Act, which required that the government provide a public notice-and-comment period for 60 days for 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 [Medicare]."[32] The government, however, argued that the appropriate standard to apply was that of the APA, which only required a notice and comment period of 30 days, and then only for "substantive rule changes," which in turn were analyzed differently by courts. Justice Gorsuch wrote the opinion of the court and found in favor of the hospitals.

Justice Gorsuch rejected the notion that the APA was the appropriate standard to apply to the case, and instead applied the standards of the Medicare Act. The key focus was on whether the change in the manual was a change of a "substantive legal standard," which in turn would have required notice and comment. Under Justice Gorsuch's analysis applying the Medicare Act, a "statement of policy" (such as the manual provision) could change a substantive legal standard, although he declined to provide a full definition of "substantive legal standard."[33] Thus, CMS could not escape its obligation to publish notice and accept public comments, and would need to comply with the requirements of the Medicare Act, rather than the APA.

The *Allina* decision, at the very least, stands for the proposition that anything published by CMS that attempts to change a "substantive legal standard" upon which payment is based must go through notice-and-comment in accordance with the Medicare Act. As applied to the Medicare enrollment context, all of the enrollment rules from regulations, to the enrollment forms, to the manuals, could be argued to implicate a "substantive legal standard governing…the eligibility of individuals, entities, or organizations to furnish or receive services…under [Medicare]," given that the enrollment process serves as an absolute barrier to payment under Medicare. Thus, if a relator or the government brought an FCA suit claiming that failure to adhere to enrollment requirements gave rise to FCA liability, a possible defense could be that the requirements themselves failed to meet the requirements of the Medicare Act under *Allina*, and thus they cannot serve as the basis for falsity under the FCA. Put another way, because the rules in question did not receive the required notice-and-comment, they cannot create a legal obligation for the supplier and thus cannot support FCA liability.

The *Allina* argument is not a silver bullet, however. In the years since the *Allina* decision was issued, courts have remained somewhat skeptical of its applicability to FCA litigation, as well as to certain types of CMS publications. For example, in *U.S. ex rel. Alt v. Anesthesia Services Associates, PLLC*[34], the District Court for the Middle District of Tennessee rejected a defendant's motion to dismiss on the

[32] 42 USCA § 1395hh(a)(2).

[33] "To affirm the judgment before us, it is enough to say that the government's argument for reversal fail to withstand scrutiny. Other questions about the statute's meaning can await other cases." *Allina*, at 579.

[34] 2019 WL 7372510 (M.D. Tenn., 2019).

grounds that a local coverage determination ("LCD"), as sub-regulatory guidance, could not form the basis for a violation under the FCA, relying on *Allina* in support of this position. Because LCDs are not promulgated using the notice and comment process, the defendant argued, they could not form the basis for an FCA action. However, the court rejected this argument, noting that *Allina* did not address LCDs, nor establish that all LCDs set forth a substantive legal standard under the Medicare Act, nor whether an LCD could form the basis for an FCA claim.

In *Agendia, Inc. v. Becerra*[35], the Ninth Circuit Court of Appeals addressed a case in which a similar argument was raised. The case did not involve FCA liability, but rather addressed a clinical laboratory's attempt to be paid for services that were denied by the MAC for failure to comply with the requirements of an LCD published by the MAC. The laboratory argued that, because the LCD had been issued without going through the required notice and comment period, it could not serve as the basis for denial of the claims. The lower court agreed, granting summary judgment and remanding to the Medicare Appeals Council for review without taking into account the LCD, but HHS appealed the decision to the Ninth Circuit. The Ninth Circuit addressed the laboratory's argument, which relied upon *Allina*, and found that LCDs did not "establish or change a substantive legal standard" (while declining to set forth an absolute definition for what constituted a "substantive legal standard").

The court, instead, addressed only whether LCDs implicated such a standard, and found that they did not. Instead, the court found that the applicable standard was the services must be "reasonable and necessary" to establish a right to payment for the provider, and that LCDs did not establish or change such standard. Rather, the court held, "[An LCD] guides the application of that legal standard in a particular claim adjudication. Specifically, it reflects a MAC's view of what qualifies as reasonable and necessary, and accordingly it controls that MAC's claims determination."[36] However, the court noted, the LCD was not binding on agency adjudicators, such as ALJs and the Medicare Appeals Council, which were instead bound by the statutory reasonable and necessary standard in their determination of whether to approve the claim. The court also noted the *Allina* case did not support the laboratory's position. Instead, it noted that, under *Allina*, the Supreme Court had noted that statutes providing the relevant standard would negate the need for notice and comment, and that such was the case with regard to the "reasonable and necessary" standard.[37]

Nevertheless, *Allina* has barely been raised within the context of Medicare enrollment as applied to FCA liability. Thus, *Allina* remains available as a potential defense to allegations of false claims premised on failure to adhere to non- or sub-regulatory guidance which has not been through the notice and comment process required under the Medicare Act. And even if *Allina* was less useful, another Supreme Court case could prove helpful in crafting effective defenses.

2.4 *Escobar* in the Defense Context

[35] 4 F.4th 896 (9th Cir., 2021).

[36] *Agendia*, at 900.

[37] *Agendia*, at 902.

In *Universal Health Services, Inc. v. U.S. ex rel. Escobar*[38], the Supreme Court issued the definitive case with respect to "implied false certification analysis" in False Claims Act ("FCA") jurisprudence. The case involved an FCA suit brought by the family of a deceased patient of a mental health clinic, acting as FCA relators. The patient had been a resident of the clinic, and had died in the clinic's custody. The patient had been prescribed certain medication to treat bipolar disorder, but died after suffering seizures requiring hospitalization. In the course of investigating the case, the patient's family discovered that many of the individuals working at the clinic were unlicensed and/or unsupervised individuals.

The false claims themselves arose within the context of Medicaid. The practitioner who had treated the patient had listed herself as a psychologist with a Ph.D., but had obtained her degree from an unaccredited internet college, and the state had rejected her application for licensure. A psychiatrist at the facility who also treated the patient, and had prescribed the medicine to treat the patient's bipolar disorder, was, in fact, a nurse who did not have prescriptive authority when not acting under supervision, and who had acted without the required supervision. In total 23 different practitioners were discovered to be lacking licenses to provide mental health services, many of whom had counseled patients and prescribed drugs for them without any supervision. All of this was in violation of certain certifications that had been made to Massachusetts Medicaid.

The central question in the Supreme Court's analysis focused on "implied false certification" theory. Did submitting a claim impliedly certify compliance with the Medicaid requirements? If so, could an implied certification serve as the basis for FCA liability? Before the decision in *Escobar*, there had been a circuit split in how to conduct the analysis of implied false certification cases.[39] With the *Escobar* decision, however, Justice Kennedy crafted a new test which turned on the issue of "materiality." The test maintains the underlying concept of an "implied false certification" which can serve as the basis for FCA liability, but the real questions are (as described in Kennedy's test): (1) whether the claim made specific representations about goods or services provided; and, (2) whether the "failure to disclose noncompliance with material statutory, regulatory, or contractual requirements make those misrepresentations misleading half-truths."[40]

Kennedy's explanation was that,

> "*The materiality standard is demanding. The [FCA] is not an 'all-purpose anti-fraud statute.'…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 pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial…In sum, when evaluating materiality under the [FCA], the Government's decision to expressly identify a provision as a condition of payment is relevant, but not automatically dispositive. Likewise, proof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the*

[38] 579 U.S. 176 (2016).

[39] For more information on the circuit split prior to *Escobar*, see, Gosfield, Alice G., ed., Medicare and Medicaid Fraud and Abuse, 2016 ed., pp. 513-520.

[40] *Escobar*, at 190.

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."[41]

Put into simpler terms, if the government knows that a statement is false, and pays the claim anyway, then that statement must not be "material." If the government would have denied payment had it known of the statement's falsity, then the statement is "material." Such an analysis relies on the specific facts of the case, as well as on the government's typical performance in response to the allegedly false statements in the case (i.e., whether the government generally pays anyway, or withholds or denies payment).

At first blush, it may seem that *Escobar* would not really apply in the enrollment context. After all, most statements within the enrollment forms themselves are explicit, rather than implicit, such as reporting of the physical location of a physician practice's office, a declaration that an individual is a 5% or greater owner or manager of the company, or the "doing business as" name of an entity. It is true that *Escobar*'s analysis does not apply to such statements. However, it is worth considering how FCA lawsuits play out in practice. In the most likely scenario involving Medicare enrollment information, a relator will file a lawsuit against a health care provider or supplier, claiming that Medicare enrollment information was incorrect, inaccurate, or was not properly updated. The subsequent submission of claims for payment implicitly certify compliance with the enrollment requirements. Thus, the theory goes, any claim submitted when the provider or supplier was not in compliance with the enrollment requirements must be false. Such an argument is potentially open to a defense under *Escobar*, surrounding the materiality of Medicare enrollment data. One would need to determine whether CMS and/or the MAC were aware of certain reported enrollment information (or information that was required, but not reported) and paid the claims anyway. If CMS or the MAC were aware and paid, the argument would be that the required information was not material.

In addition to the implied statement of compliance with enrollment requirements inherent in a Medicare claim for payment, the enrollment forms themselves also include certain implicit statements. For example, the enrollment regulations require certification of compliance with "Federal and State licensure, certification, and regulatory requirements as required, based on the type of services or supplies the provider or supplier type will furnish and bill Medicare."[42] This could include, for example, compliance with state laws and doctrines, such as the corporate practice of medicine doctrine and compliance with related requirements to form professional corporate entities. Were a suit to be brought claiming violation of the corporate practice of medicine, and thus false claims stemming from the false certification of compliance with state law, it could raise a host of questions under *Escobar*. For example, how much attention does CMS actually pay to state law compliance as a basis for denial of payments? Does CMS, or the relevant MAC, actually refuse to pay when it knows an entity is not in compliance with

[41] *Escobar*, at 194-195.

[42] 42 CFR § 424.516(a)(2).

state corporate practice requirements? If CMS does deny such payments, it would further trigger an analysis under applicable state law as to whether corporate practice doctrine had actually been violated.

3.0 Regulatory Hierarchy Overview

As discussed above, the rules governing Medicare enrollment can be found in three major sources: (1) the regulations, (2) the enrollment forms, and (3) the manuals. Most Medicare Part-B enrollment regulations can be found at 42 CFR §§ 424.500, et seq.[43] The language in the regulations is legally binding, and goes through notice and comment.[44] Nevertheless, the language in the preface to the regulations is not legally binding, and instead should be read as informative guidance from CMS. Put another way, a failure to adhere to the plain text of the regulations may be considered a violation; adherence to the text of the regulations without also meeting the guidance found in the preface to the regulations is not necessarily a violation.

3.1 The Forms

At first blush, one might think that the CMS-855 series of forms (and their electronic embodiment in PECOS) are simply the mechanism by which the regulations are implemented, and are themselves further construed by the manuals. In fact, the forms themselves generally go through a notice and comment process, although this occurs in accordance with the requirements of the Paperwork Reduction Act of 1995 ("PRA")[45], rather than the Medicare Act.

As of this writing, the PRA actually requires more notice than the Medicare Act. Specifically, whereas the Medicare Act requires a single 60-day notice period[46], the PRA requires two separate notice and comment periods: one with a length of 60 days[47], and second and subsequent notice period with a length of 30 days.[48] For example, the CMS-855I and CMS-855O were each revised in 2023. Preceding these revisions, CMS published two notices soliciting public comment regarding proposed changes to the forms. The first was published on September 21, 2022, with a comment deadline of November 21,

[43] Part-A enrollment regulations can be found at 42 CFR §§ 489.1, et seq.

[44] Although the precise *length* of notice and comment periods might offer an opportunity for defense, depending on whether it extends to 60 days or more, as required under the Medicare Act.

[45] P.L. 104-13.

[46] 42 USCA § 1395hh(a)(2).

[47] 44 USCA § 3506(c)(2)(A). "With respect to the collection of information and the control of paperwork, each agency shall…provide a 60-day notice in the Federal Register, and otherwise consult with members of the public and affected agencies concerning each proposed collection of information…"

[48] 44 USCA § 3507(b). "The Director [of OMB] shall provide at least 30 days for public comment…" Note, however, that the relevant agencies proposing to collect information under § 3506(c)(2)(A) typically are the ones who publish the notice soliciting comment.

2022.[49] The second was published on December 21, 2022, with a comment deadline of January 20, 2023.[50]

Thus, the procedures to which CMS is adhering in compliance with the PRA result in it satisfying the requirements of the Medicare Act for notice and comment, at least with respect to the CMS-855 series of forms. This has the overall effect of weakening an *Allina* based argument against the forms themselves, in the event that a defendant wishes to challenge their validity. However, this does not foreclose the possibility of the currently-aligned sets of requirements diverging at some point in the future due to statutory amendments. For example, if the PRA were to be amended to dramatically reduce the required length of notice, or to eliminate it altogether, or if the Medicare Act were amended to lengthen the amount of notice required to more than 90 days total or to require a single notice period of 90 days (rather than one period of 60 days and one period of 30 days), CMS would still need to adhere to the Medicare Act's requirements. If it did not, and instead published updates to the CMS-855 forms without providing the notice and comment required by the Medicare Act specifically, this would open the door for a challenge to the forms under *Allina*.

3.2 The Manuals

Below the regulations and the forms lie the Medicare manuals, which are published by CMS (as opposed to the MACs in their various jurisdictions). The Medicare manuals are written as guidance for the MACs, and not as instructions or requirements for providers or suppliers, although many relators treat Medicare manuals as equivalent to statutory requirements. However, the non-binding nature of the manual provisions with respect to providers and suppliers becomes obvious when one reads the actual language of the manuals themselves.

For example, the manuals describe how long a MAC has to process paper claims as opposed to electronic claims submitted through PECOS. For paper forms, the manuals instruct that, if a site visit is required, 95% of all paper forms for initial and change-of-information applications must be processed within 65 calendar days of receipt of the application by the MAC, and 100% within 100 calendar days. If no site visit is required, 95% must be processed within 30 calendar days, and 100% must be processed within 65 days.[51] By contrast, for electronic applications, if a site visit is required, 95% must be processed within 50 calendar days, and 100% must be processed within 85 calendar days. If no site visit is required, 95% must be processed within 15 calendar days, and 100% within 50 calendar days.[52] None of these requirements apply to *suppliers*. While a supplier having an understanding of what they can expect as far as processing times for their enrollment applications go, these are entirely requirements for the MACs, and not binding upon suppliers in any way.

Other provisions within the manuals may appear to bind suppliers, but again are merely instructions for MACs regarding how to approach interactions with suppliers in different circumstances.

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[49] 87 Fed. Reg. 57700 (September 21, 2022).

[50] 87 Fed. Reg. 78109 (December 21, 2022).

[51] Medicare Program Integrity Manual, Ch. 10, § 10.5(A)(1).

[52] Medicare Program Integrity Manual, Ch. 10, § 10.5(A)(3).

For example, there is a requirement when completing a Medicare enrollment application to list an "authorized official."[53] The manual explains that "An authorized official must be a 5 percent direct owner, chairman of the board, etc., of the enrolling supplier with the authority to bind the supplier, both legally and financially, to the requirements set forth in 42 CFR § 424.510."[54] The manual then further describes how the authorized official must also have an ownership or control interest in the supplier (e.g., as a general partner, CFO, etc.), not in a parent company alone, and then cites to 42 CFR § 424.502 and the definition of "authorized official," noting that an authorized official can be more than just someone with one of the titles outlined in the manual, and could include other titles, such as "executive director," "administrator," or "president." Finally, the manual reminds the MAC to "consider the individual's title as well as the authority granted by the organization when determining whether an individual qualifies as an authorized official," and further describes how to respond if the MAC is unsure of an individual's qualifications to be an authorized official.[55] The focus on instructions to MACs in applying the regulations is the purpose of the manuals. The manuals are not meant to be prescriptive or authoritative for suppliers.

This view has been borne out in caselaw as well. In *Christensen v. Harris County*[56], the Supreme Court addressed a case involving whether under the Fair Labor Standards Act ("FLSA"), employees of a political subdivision could be forced to schedule time off to avoid the political subdivision needing to pay the employees for unused time off, as required by the FLSA. Without getting into the particulars of the FLSA's requirements, the case involved a Texas county attempting to require their deputy sheriffs to use paid time off in a certain way, to avoid having to pay for unused paid time off (which the county could not afford to pay). The deputy sheriffs sued, claiming that this action violated the FLSA. The county had sought advice from the Department of Labor's Wage and Hour Division, which issued an opinion letter taking the position that "neither the statute nor the regulations permit an employer to require an employee to use accrued compensatory time."[57] The deputy sheriffs attempted to rely on this guidance, claiming that it was due deference under the Court's prior opinion in *Chevron U.S.A., Inc. v Natural Resources Defense Council, Inc.*[58] However, the Court rejected this view. Most significantly for purposes of approaching the legal power of Medicare's manuals, the Court noted that, "Interpretations such as those in opinion letters – like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law – do not warrant *Chevron*-style deference…Instead, interpretations contained in formats such as an opinion letter are entitled to respect…but only to the extent that those opinions have the power to persuade."[59] Thus, at a baseline, Medicare's manuals are merely persuasive authority, rather than legally binding authority, as stated by

[53] The definition of which can be found at 42 CFR § 424.502.

[54] Medicare Program Integrity Manual, CH. 10, § 10.3.1.2.8(A).

[55] Medicare Program Integrity Manual, Ch. 10, § 10.3.1.2.8(A).

[56] 529 U.S. 576 (2000).

[57] *Christensen*, at 581.

[58] 467 U.S. 837 (1984).

[59] *Christensen*, at 587.

the Supreme Court. There is, however, another wrinkle that must be addressed with respect to Medicare's manuals.

In general, courts have deferred to agency interpretations, although there are some nuances to this deference and recent critical changes. For decades, courts were instructed to defer to agency interpretations of ambiguous statutory language under the Supreme Court's opinion in *Chevron USA, Inc. v. National Resource Defense Council, Inc.*[60] Recently, however, *Chevron* was overturned by the Court's opinion in *Loper Bright Enterprises v. Raimondo*.[61] It is worth noting that *Chevron* and *Loper Bright* both focus on the APA, with *Loper Bright* overturning *Chevron* due to language within the APA. Under *Allina*, however, the relevant statute to consider in analyzing Medicare regulations is expressly not the APA, but rather the Medicare Act.

The government's reliance on the APA in *Allina* likely was driven by what has been referred to as the "Richardson Memorandum." In 1971, the then-Department of Health, Education, and Welfare ("DHEW") published a Statement of Policy providing notice that the Department would voluntarily comply with the notice and comment requirements of the APA, even though the Department was exempted from such requirements at the time.[62] The issuance of this statement also pre-dated the passage of the 1987 amendments to the Medicare Act that imposed the 60-day notice-and-comment period that were the focus of *Allina*.[63] DHEW and later HHS (its successor entity) continued to adhere to this statement until March 3, 2025, when the Richardson Memorandum was rescinded.[64] Thus, as of this writing, The Department of Health and Human Services – along with CMS – is no longer binding itself to the notice and comment requirements of the APA.

Yet, the government cannot so easily evade its obligations under the Medicare Act. To the contrary, with respect to Medicare enrollment and the regulations and processes surrounding it, the Medicare Act itself requires that "The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this subchapter."[65] With respect to the Medicare enrollment forms themselves, the statute states "The Secretary shall consult with providers of services and suppliers before making changes in the provider enrollment forms required of such providers and suppliers to be eligible to submit claims for which payment may be made under this subchapter."[66] These statutory requirements establish the authority for CMS to issue both the enrollment regulations and the

[60] 467 U.S. 837 (1984).

[61] 603 U.S. 369 (2024).

[62] 36 Fed. Reg. 2532 (February 5, 1971).

[63] P.L. 100-203 § 4035. Originally, the notice period was even longer, at 90 days. This was later revised down to 60, which is the current requirement.

[64] 90 Fed. Reg. 11029 (March 3, 2025).

[65] 42 USCA § 1395cc(j)(1)(A).

[66] 42 USCA § 1395cc(j)(1)(C).

enrollment forms, but likewise mandate that they each be provided with 60 days of notice and comment.[67]

Nevertheless, with respect to the validity of Medicare's manuals, while they may be seen as "persuasive" authority under *Christensen*, a prior Supreme Court case, *Auer v. Robbins*[68], must also be considered. Relators may seek to convince a court that, while *Chevron* deference may not be relevant, *Auer* deference is. In *Auer*, the Court addressed another case involving the FLSA, again involving the matter of law enforcement officers and payment for overtime work. At the request of the Court, the Secretary of Labor filed an *amicus* brief to interpret the relevant regulation, and the Court held to that interpretation, explaining "Because the [rule at issue] is a creature of the Secretary's own regulations, his interpretation of it is, under our jurisprudence, controlling unless plainly erroneous or inconsistent with the regulation. That deferential standard is easily met here."[69] The problematic implication of *Auer* to Medicare enrollment, and specifically to the Medicare manuals, is that it could be argued to require deference to agency interpretations (i.e., the manual provisions) of the agency's own regulations. To be clear, the distinction between *Loper Bright* and *Auer* is that *Loper Bright* addresses deference due to agencies in the interpretation of statutes through their issuance of regulations, while *Auer* addresses deference due to agencies in the interpretation of their own regulations as interpreted by sub-regulatory guidance. As such, *Auer* will be relevant in discussions of deference towards CMS manuals.

However, in 2019 *Auer* was reined in by the Supreme Court in *Kisor v. Wilkie*[70], noting that "the deference doctrine…is potent in its place, but cabined in its scope."[71] The opinion, written by Justice Kagan, barely addressed the actual facts of the matter, preferring instead to delve more deeply into whether it was overturning *Auer* (which it did not), and how *Auer* is circumscribed. In the opinion, Justice Kagan illustrated circumstances in which *Auer* deference would be applied, primarily revolving around regulatory ambiguity (e.g., the Americans with Disabilities Act requiring stadiums to construct seating that provides lines of sight comparable to those for members of the general public, and whether that applied to wheelchair seating that took into account when patrons rise to their feet during a basketball game), or applications of a rule to precise edge cases (e.g., whether the Transportation Safety Authority's requirement that liquids and gels in a carry-on bag be inside a clear plastic bag applied to truffle pâté).[72] In such situations, generally speaking, Justice Kagan described that courts defer to agency interpretations of their own regulations under *Auer*. However, "Auer deference is not the answer to

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[67] The current administration may think that, by rescinding the Richardson Memorandum, it has executed a clever end-run around the need to provide any notice and comment as applied to many of the various agencies under the aegis of the Department of Health and Human Services. It may, instead, find that it is subject to a far more complex and varied set of requirements under other statutes, such as the requirement to provide 60 days of notice and comment for changes to Medicare, as required by the Medicare Act, specifically 42 USCA § 1395hh(a)(2).

[68] 519 U.S. 452 (1997).

[69] *Auer*, at 461, citing *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332 (1989), itself quoting *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 420 (1945), internal quotation marks omitted.

[70] 588 U.S. 558 (2019).

[71] *Kisor*, at 563-564.

[72] *Kisor*, at 567.

every question of interpreting an agency's rules."[73] Where uncertainty or ambiguity does not exist, courts should not apply *Auer* deference. "If uncertainty does not exist, there is no plausible reason for deference…If there is only one reasonable construction of a regulation…then a court has no business deferring to any other reading, no matter how much the agency insists it would make more sense. Deference in that circumstance would 'permit the agency, under the guise of interpreting a regulation, to create *de facto* a new regulation.'"[74] Courts must likewise exhaust all traditional tools of construction before determining that a rule is genuinely ambiguous, and the agency's reading of the rule must still be reasonable.[75]

Again, it is worth recalling how Medicare's enrollment rules – especially the Medicare manuals – are actually used in FCA litigation. Often, relators point to the manuals as legally binding authorities, claiming that a failure to adhere to the "requirements" of the manuals means that any claims submitted in violation of manual instructions are false. When this argument is advanced, relators' counsel may attempt to rely upon *Auer*, which may represent something of an attractive distractor for courts. Without needing to wade into the murky waters of administrative interpretation, *Auer*, even as limited by *Kisor* and *Christensen*, offers an easy off-ramp for the court in deferring to agency interpretation, and towards considering Medicare manual language as authoritative enough to support allegations of FCA liability for failure to comply with the "requirements" of the manuals.

However, there are counter arguments. First, with respect to the Medicare manuals, defense counsel can argue that *Auer* – limited or otherwise – does not permit sidestepping the requirements of the Medicare Act as described in *Allina*. The Medicare Act requires 60 days of notice and comment for any change to a "substantive legal rule" that would impact, among other things, payment or eligibility for payment like Medicare enrollment requirements. While Justice Gorsuch may not have seen fit to define "substantive legal standard" in *Allina*, certainly using the Medicare manuals to create additional sub-regulatory requirements for providers and suppliers in a manner that would support FCA liability if they failed to meet such requirements must qualify as establishing a "substantive legal standard." If a requirement where failure to comply renders all claims submitted "false" is not a "substantive legal standard," then "substantive legal standard" has no real meaning.

In the event that an appeal to *Allina* is unsuccessful, one could still challenge the appropriateness of *Auer* deference in the application of Medicare manual language, provided that the regulatory language itself was clear and unambiguous. As will be more fully discussed below, aspects of both the regulations and the forms themselves are not ambiguous.

3.3 Why Does the Hierarchy Matter?

Having a grasp of the hierarchy of documents can be useful, even essential, in representing clients and in deploying the various legal defenses addressed above. Moreover, there are instances in which the hierarchy of documents is potentially in conflict with itself, or at least there are questions surrounding which level within the hierarchy actually controls. When this is the case, the *Escobar* and

[73] *Kisor*, at 573.

[74] *Kisor*, at 574-575.

[75] *Kisor*, at 575.

Allina cases may offer potential defenses. Moreover, a better understanding of the nature of the hierarchy of documents – including where they are in conflict, or at least not perfectly aligned – can be useful in providing practical advice to clients.

Consider the concepts of "effective date of billing privileges" and "retrospective billing date." The regulatory language for these concepts is relatively clear. The regulations state that the "effective date of billing privileges" is the later of (1) the date of filing of a Medicare enrollment application that was subsequently approved by the MAC, or (2) the date that the supplier first began furnishing services at a new practice location.[76] For retrospective billing, the regulations state that suppliers may retrospectively bill for services when they met all program requirements and services were provided at the enrolled practice location for up to 30 days prior to their effective date, unless circumstances precluded enrollment in advance of providing services to Medicare beneficiaries (although the regulations provide no examples of what constitutes such "circumstances").[77] The lack of a definition for such "circumstances" notwithstanding, the language in each of these regulatory sections is otherwise clear and unambiguous.

When discussing "effective date of billing privileges," the Medicare manual mirrors the regulatory language. However, things become murkier when the manual addresses the concept of "retrospective billing date." First, the manual defines the "circumstances" that would preclude enrollment, where the regulations remain silent. In this regard, the manual instructs the MAC to interpret this regulatory language to mean that the supplier met all program requirements *and* that no final adverse action[78] precluded enrollment. If such an action did preclude enrollment, the MAC is instructed to establish effective billing dates the day after the final adverse action was resolved, as long as it is not more than 30 days prior to the application submission date.[79]

The manual further attempts to illustrate the distinction between "retrospective billing date" and "effective billing date." The manual offers an example involving a supplier that begins to render services at a location on March 1, and submits an enrollment application on May 1, which is then approved on June 1. The effective date in this case is May 1, and the retrospective billing date is April 1. Up until this point, the distinction is easily understood. Moreover, the manual's defining of the "circumstances" is reasonable, and would likely be entitled to *Auer* deference, as an explanation of a regulation which contains within it an undefined term. However, the manual continues, stating, "The effective date entered into PECOS and the Multi-Carrier System will be April 1; claims submitted for services provided before April 1 will not be paid."[80] This raises potential confusion.

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[76] 42 CFR § 424.520(d)(1).

[77] 42 CFR § 424.521(a)(1).

[78] Defined as: a Medicare-imposed revocation of any Medicare billing privileges; suspension or revocation of a license to provide health care by any State licensing authority; revocation or suspension by an accreditation organization; a conviction of a Federal or State felony offense (as defined in 42 CFR § 424.535(a)(3)(i)) within the last 10 years preceding enrollment, revalidation, or re-enrollment; or, an exclusion or debarment from participation in a Federal or State health care program. 42 CFR § 424.502.

[79] Medicare Program Integrity Manual, Ch. 10, § 10.6.2(B)(3).

[80] Medicare Program Integrity Manual, Ch. 10, § 10.6.2(B)(3).

In most cases, when a supplier enrolls in Medicare, the MAC will send the supplier a letter indicating that their enrollment application has been approved, and stating their effective date of billing privileges and, in some instances, their retrospective billing date. But what happens if the supplier loses this letter? How is the supplier to determine (A) their effective date of billing privileges, and (B) their retrospective billing date? The most likely sources to which the supplier will turn are the PECOS system, or potentially the relevant MAC's own website if it offers search tools to provide such information. But the date on the PECOS system is, at least according to the language of the manual, inaccurate. Recall the language of the Medicare manual: while the title of the date recorded on PECOS may read "effective date of billing privileges," that date actually reflects the retrospective billing date, and not the supplier's actual effective date of billing privileges (which is 30 days prior to the date listed on PECOS), and no retrospective billing date will be listed on PECOS at all. The date available on the MAC's website might likewise be unclear, or might reflect a different date from PECOS as the effective date of billing privileges. So, which date is the official "effective date of billing privileges"? On which date can the supplier rely, if they want to retrospectively bill?

This issue is further confused when one considers that the initial letter from the MAC itself can provide incorrect information! More specifically, MACs sometimes send an initial enrollment letter stating that a supplier's "effective date of billing privileges" is a date 30 days prior to the submission date of the enrollment application – in other words, the "effective date" in the letter is actually the retrospective billing date. The problem is common enough that CMS includes in its manuals specific guidance that "It is important that the contractor keep in mind the distinctions between: (1) the date of enrollment/approval; (2) the effective date of billing privileges under 42 CFR § 424.520(d); and (3) the date from which the supplier may retrospectively bill for services under § 424.521(a)."[81]

So, if a supplier is attempting to determine their actual effective date of billing privileges, which statement should the supplier rely upon; and which is legally binding? The answer depends on the supplier's circumstances and goals. If an attorney is advising the client prospectively with regards to avoiding headaches with CMS and the MACs, the best advice would be to follow the manual language and to not attempt to bill for any services rendered earlier than the date stated in the letter, or the date that appears in PECOS. Certainly, claims will *probably* not be paid if submitted for dates of service prior to the PECOS date. This advice – falling squarely within the "general advice" approach – would be the least likely to cause problems with CMS and the MAC. It does not necessarily need to address which of the statements is legally binding on the supplier. Instead, it simply takes the more conservative view that the supplier should not attempt to submit claims for dates of service prior to the date recorded in PECOS.

By contrast, one can imagine circumstances in which a supplier has already submitted claims for dates of service prior to the PECOS date, or where the PECOS date itself is incorrectly recorded due to the MAC's own internal confusion and the supplier has been paid for claims rendered during a period that extends more than 30 days prior to the actual effective date of billing privileges.

As a practical matter, one would expect that under normal circumstances, a claim submitted for services with a date of service prior to the date in the PECOS system would be automatically rejected by the Medicare payment system; there would be no way for the provider to receive a payment, and thus no claim, false or otherwise. However, given that MACs have been known to report incorrect dates in

[81] Medicare Program Integrity Manual, Ch. 10, § 10.

approval letters sent to suppliers (e.g., where the "effective date of billing privileges" is actually 30 days prior to the date their application was received), one must wonder whether MACs also mistakenly enter incorrect dates into the PECOS system. While it would seem unlikely that a MAC would later discover this error and pursue a false claims action, such circumstances could easily give rise to a whistleblower action.

In terms of crafting a defense under *Escobar*, the submission of a claim itself would be an "implied certification" that one is eligible for payment, i.e., that the supplier's claim was rendered within the retrospective billing date window or after the effective date of billing privileges. If a claim submitted prior to the PECOS date was paid, the argument would be that the language of the manual was not "material," because the MAC knew or should have known the correct application filing date, and from that should have known the correct retrospective billing date, but paid the claim anyway. A similar argument could be applied in a situation where the recorded PECOS date was itself recorded incorrectly by the MAC. Again, the argument in such circumstances would attempt to sidestep the morass presented by conflicting application receipt dates, actual and recorded effective dates of billing privileges, and the inaccuracy of the date reflected in the PECOS database. Instead, the argument would be that the government knew or should have known what the correct information was, and simply did not deem it "material" enough to mind the details, leading to the claim being paid in spite of what it should have known.

Arguing in the alternative, one could approach such circumstances from the perspective of *Allina*, and argue that the language of the manual cannot be binding upon a supplier (even if it reflects CMS' and the MAC's interpretation of its own regulations), and that it is appropriate and reasonable for the supplier to rely upon (A) the date stated in the initial enrollment letter, (B) the date listed in PECOS using the regulatory interpretation of "effective date of billing privileges," or (C) a date stated on the MAC's website.

In either the scenario where the supplier has billed and been paid erroneously for claims with dates of service up to 30 days prior to the date reflected in PECOS, or the scenario where the PECOS date was incorrectly recorded by the MAC and the supplier was paid, a relator might argue that the supplier has violated Medicare's requirements, citing the manual language in support of the relator's argument. Such an argument foists onto the supplier the responsibility for knowing either the content of the manuals, or for knowing the correct dates involved, in spite of what might be multiple conflicting government sources of information.

In the scenario where the PECOS date is correct but the supplier was accidentally paid anyway, the argument would be that the supplier should know (based on the manuals) that the PECOS date means "retrospective billing date" even though it says "effective date of billing privileges." As absurd as this sounds, it is not difficult to imagine a relator making such an argument. Similarly, in the scenario where the PECOS date is wrongly recorded, the whistleblower might argue that the supplier still has a duty to know, based on their actual date of application receipt, what the correct dates should be, regardless of what PECOS or the acceptance letter says.

In response, the supplier could raise the argument that the regulatory language is ultimately what controls, and that the supplier has complied with the regulations and submitted claims within the appropriate date ranges based on the information presented to them in PECOS. Any attempt to impose upon the supplier a duty to adhere to the language of the manuals, either by imputing knowledge the supplier should have regarding the actual meaning of PECOS' "effective date" or extrapolating from what

the supplier already knows about the date on which their application was received, is an attempt to make from the manual language a "substantive legal standard" that implicates eligibility for payment under Medicare. In such circumstances, without having gone through the notice and comment process as required under the Medicare Act and the *Allina* decision, the language of the manual could not be said to trump the plain language of the regulations.

4.0 Practical Advice & Real-World Scenarios

With respect to Medicare enrollment, most clients face two different types of risk: (1) an interruption of billing privileges due to some failure to initially record or maintain information required on the enrollment application; and (2) the risk of retained overpayments and FCA liability. Understanding both the history of the Medicare program's enrollment requirements, as well as the hierarchy of documents, can be critical to managing both sets of risks for clients. However, there are defenses and lessons to be learned from actual experiences of supplier clients.

First, with interrupted billing privileges, the most common scenarios involve missed reporting deadlines and/or failures to file updates to the enrollment information, leading to deactivation of billing privileges, or worse. This usually occurs because the supplier has failed to report a change in their information, or failed to respond to a revalidation request. Changes to practice locations, changes in ownership (including with respect to authorized or delegated officials), and changes to adverse final actions must be reported within 30 days of the change occurring. All other changes in information must be reported within 90 days.[82] Revalidation requests must be responded to within 60 calendar days of the date of the request.[83] Once these deadlines are missed, the MAC may deactivate billing privileges. Once deactivated, billing privileges can be reactivated by filing a complete new application, or attempting to rebut the deactivation by proceeding through the appeals process.[84]

Second, with respect to overpayments and FCA liability, the main concern stems from whistleblowers, although MAC audits can also give rise to such liability. Most often, the whistleblower is someone who works or previously worked for the supplier. This individual witnesses something that they think constitutes a violation of Medicare's rules (in this case, the enrollment requirements), and so brings a False Claims Act suit. In the enrollment context, this can arise from how enrollment is handled for different types of clinicians, as well as failures to maintain up-to-date enrollment records, either of which gives rise to FCA liability for claims submitted when the supplier would not have normally been eligible for billing privileges, and thus able to be paid in the first place. Put another way, the broad strokes of a whistleblower's argument in the enrollment arena is that each claim submitted during this period is an implicit statement that the supplier is in compliance with Medicare's enrollment requirements, and if the government had known that the supplier was not in compliance, it would not have paid.

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[82] 42 CFR § 424.516(e)(1), (2).

[83] 42 CFR § 424.515(a)(2).

[84] 42 CFR § 424.540(b)(2). For more on the enrollment system's appeals process, see Shay, Daniel, "'Halt! Who Goes There?' – Coping with the Continuing Crackdown on Medicare Enrollment," Health Law Handbook, Thompson Reuters pub., 2011 ed., pp. 71-102.

4.1 Scenario 1: Harry Doesn't Work Here Anymore

Several years ago, our firm represented a physician practice with multiple partner physicians. One of the partners ("Harry," for purposes of this discussion) had left the practice in the late 1990s. However, Harry had not been removed from the practice's enrollment records; he still was listed as a physician who reassigned his right to payment to the practice, even though he had moved far away. Around the early 2000s, however, Harry apparently lost his license to practice medicine wherever he had ended up. As a result, our client, Harry's old practice, received a letter from the MAC stating that the practice would have its billing privileges revoked for a failure to report an final adverse legal action within 30 days. If Harry had still worked for the practice, the practice would have been up the proverbial creek without a paddle.

However, we were able to contact the MAC directly by telephone, and speak to the enrollment specialist who had sent the letter, explaining the situation. However, we also checked the history of Medicare's enrollment requirements. At the time that Harry had left, there was no requirement to remove him from reassignment in the regulations, the manuals, or the enrollment forms themselves. We also explained this to the MAC. We offered to provide the MAC with a sworn affidavit, along with cancelled pay stubs for Harry's last paychecks. This satisfied the MAC which closed the case and reactivated the practice's billing privileges, allowing them to submit claims for the entire period.

The best outcome would have been if the practice had stayed current on its reporting obligations all along. For example, if the practice had conducted its own periodic enrollment record checks, and submitted updates as needed, they would have seen Harry's name on their records and removed him (ideally prior to his loss of licensure). But the next best outcome – essentially a "no harm, no foul" result from the MAC – was able to be achieved in part because we were able to demonstrate how the enrollment rules at the time Harry left did not require reporting his departure at all, which we were able to demonstrate by virtue of knowing the history of the enrollment requirements.

4.2 Scenario 2: Lost in the Mail

The facts of this scenario are modified from the actual facts, but are based on a different representation in which our firm was engaged. The scenario involves a physician practice with a single physician owner, and several non-physician practitioners employed by the practice. The physician died suddenly, throwing the practice into turmoil as it had to scramble to deal with a host of issues. In the midst of the chaos, the practice administrators neglected to remove the deceased physician from the enrollment records, leading to the MAC contacting the practice and requesting that it update its records. The practice did so, submitting the requested update by paper to the address listed in the MAC's letter, but the update was lost in the mail. The MAC followed up months later, informing the practice that its billing privileges had been deactivated, and telling the practice that it could submit a rebuttal letter if it wanted to. The practice was unsure what to do, and contacted us.

Initially, the practice thought to throw itself upon the mercy of the MAC and ask for another chance, informing the MAC that it had sent in the application but that the application had been lost by the postal service. This approach, however, is usually unsuccessful with MACs, and they are unsympathetic to requests for clemency if the requirements of the regulations clearly weren't met.

Without proof that the rebuttal had been submitted, there was absolutely no chance the MAC would believe the practice, and even with proof it would be unlikely to work.[85]

The best alternative was to re-file, this time electronically. Electronic filing made more sense based on two factors. First, there is no way to "lose" an electronic filing. Submission and receipt would be guaranteed. Second, processing times for electronic filings are generally faster than paper filings. Paper applications can take up to 65 calendar days, and at least 30 in many cases. Electronic applications, by contrast, are usually processed within 15 days and 50 at the longest.[86]

A further wrinkle, however, was the need to hire a new physician before submitting the application. Because the application requires compliance with state law, and the state in question had a "corporate practice" doctrine applicable to most licensed professions, the practice needed a licensed physician to be its owner. While one could potentially defend an argument about the materiality of certain state laws to the enrollment process, the goal in this instance was simply to get the practice's deactivation resolved as quickly and smoothly as possible, while also minimizing any possible exposure to future problems.

This scenario illustrates the difference in the "general advice" approach as opposed to the "legal defense" approach. What the practice needed was practical advice as to how best to (1) ensure a swift return to being able to bill for services, and (2) a way to ensure #1 without running afoul of potential future liability for failing to properly enroll in the first place. Discussions about what positions might be legally defensible (e.g., whether the practice raise an *Escobar* materiality challenge to the state corporate practice of medicine issue) were beside the point; what mattered was reactivating billing privileges as quickly as possible, while simultaneously minimizing legal exposure as much as possible.

4.3 Scenario 3: Reassignment Whistleblower

In this scenario, a physician group faced allegations of FCA violations brought by an ex-employee who had only worked for the group briefly before being fired. Our firm was consulted as expert witnesses in the case, and I served as an expert witness on matters pertaining to Medicare enrollment. Among the relator-employee's allegations were various failures to comply with Medicare's enrollment rules, among them the failure to record certain data pertaining to reassignment of billing privileges. More specifically, the relator claimed that the group had failed to report Provider Transaction Access Numbers (PTANs) on enrollment forms and failed to associate reassigning physicians with PTANs for the group's offices.

As a brief explanation, Medicare uses PTANs as additional identifiers in a manner similar to the NPI. Individual practitioners are assigned PTANs, as well as group practices, although a group practice may have multiple PTANs when it has multiple offices. However, PTANs are only issued to group practice office locations when that office location is in a different payment locality from other group practice locations; if every location is within the same payment locality, the group will only have one PTAN even though it may have multiple office locations within a given payment locality.

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[85] For examples of instances where MACs and administrative law judges have been similarly unsympathetic, see Shay, Daniel, "'Halt! Who Goes There?' – Coping with the Continuing Crackdown on Medicare Enrollment," Health Law Handbook, Thompson Reuters pub., 2011 ed., pp. 71-102

[86] Medicare Program Integrity Manual, Ch. 10, §§ 10.5(A)(1)(b); 10.5(A)(3)(b).

There is no regulatory obligation to record PTANs as part of supplier enrollment. In fact, the phrase "PTAN" and "Provider Transaction Access Number" do not appear anywhere in the supplier enrollment regulations. Medicare enrollment forms have included blanks where a PTAN could be entered when a physician or other practitioner was reassigning their right to payment to a group, but the forms in question have not consistently required the submission of this information, depending on which version of the form, and instead most versions of the form made such reporting optional. Because the alleged false claims spanned a period of time during which different versions of the form were in use, the defense argument was that when reporting of a PTAN was optional, it could not serve as the basis of FCA liability.

Moreover, even the Medicare manuals did not support the relator's argument, because they too did not reflect any requirement to report PTANs when reassigning as part of the enrollment process. One of the relator's experts argued that such an obligation did exist in the manuals, but that obligation did not appear in the manuals until 2023, which was outside the time frame of the alleged false claims. Had the language appeared earlier, however, it would have been open to a challenge under *Allina*, and even under *Auer* and *Kisor*. First, as has been discussed, the manuals do not go through the notice and comment period. But second, when the forms – which do go through notice and comment – make reporting a PTAN optional, the manual language could not make that optional reporting into a requirement and survive an analysis under *Auer* and *Kisor*. The form itself is unambiguous, and the regulations do not even raise a question about the obligation to report PTANs; no such requirement exists at all.

However, what the relator actually relied upon was neither the forms nor the manuals, but rather a CMS Frequently Asked Questions document that was included as part of a presentation given in Nashville in 2019, and which was later made available on CMS' website.[87] Put simply, there is no way that such a document could survive a challenge under *Allina*. The FAQ in question absolutely did not go through notice and comment as required under the Medicare Act, and the use of such a document as a legally binding requirement on Medicare suppliers sufficient to create an obligation, the violation of which would create FCA liability should not withstand scrutiny by a court applying *Allina* properly. Moreover, such circumstances could give rise to a materiality challenge under *Escobar*. If, in the normal course of business, CMS and MACs pay claims for services even when no PTAN has been reported as part of the reassignment process, one could hardly characterize the omission of PTAN data as "material" to the claim.

5.0 Conclusion

The Medicare enrollment process, much like the rest of the system, is byzantine, layered, and difficult to navigate. Between regulatory requirements, enrollment form requirements themselves, and manual language construing both (to say nothing of additional sub-regulatory guidance like FAQs, MedLearn Matters articles, etc.), having a clear understanding of the process can be difficult for health care clients. For counsel to be effective in these areas, it is immensely helpful to have a grasp not only of the current requirements, but of the history of the enrollment process and the documentation that

[87] National Provider Enrollment Conference, Frequently Asked Questions, Question #7, Nashville, TN, March 12-13, 2019), available at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/2019_National_Provider_Enrollment_Conference_FAQs.pdf.

underpins it, including both the forms and manuals. This understanding can assist in providing general guidance, but can be essential in crafting legal defenses against allegations of FCA violations. Towards this end, the ability to lay hands on older copies of enrollment forms and manual language can be just as important as understanding the Supreme Court jurisprudence that may provide defenses for clients.