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False Claims in Healthcare
Chapter 4. Common FCA Issues

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This chapter addresses common types of false claims as well as best practices to avoid False Claims Act (FCA) liability. Topics include: (1) upcoding, which has been a major focus of the enforcement efforts of the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG); (2) medical necessity theories of FCA liability, which typically fall under the "false certification" theory wherein a defendant faces liability for falsely asserting that it has complied with a statute or regulatory requirement by submitting a claim; (3) the "worthless services" theory of FCA liability, which is a relatively new theory that federal courts are increasingly reviewing; and (4) FCA liability related to outpatient observations vs inpatient admissions. This chapter does not address overpayments that must be reported and returned under the Patient Protection and Affordable Care Act's (ACA) 60-day rule. The 60-day rule is discussed in detail in Chapter 6, "The Medicare and Medicaid Overpayment 60-Day Report and Return Statute."

Upcoding

Upcoding is a common type of false claim, which refers to the practice of providers assigning billing codes for more expensive medical procedures or treatments or for services of a greater quantity or duration than what was actually provided to patients in order to increase the amount of reimbursement.

For instance, Medicare pays for many physician services using evaluation and management (E&M) codes. New patient visits generally require more time than follow-up visits. As such, E&M codes for new patients are reimbursed at a higher rate than for established patients. Under this paradigm, upcoding would exist where a physician provides a follow-up office visit or follow-up inpatient consultation but bills using a higher-level E&M code meant for a new patient office visit or an initial inpatient consultation.

Upcoding has been a major focus of the enforcement efforts of the OIG. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) added another civil monetary penalty to the OIG's sanction authorities for upcoding violations.[4] Since then, upcoding has been at the heart of numerous and notable FCA settlements and litigation.

In a massive settlement from August 2018, Prime Healthcare Services Inc., Prime Healthcare Foundation Inc., Prime Healthcare Management Inc. (Prime), and Prime's founder and CEO agreed to pay the US government $65 million to resolve civil FCA allegations. According to a 2018 U.S. Department of Justice (DOJ) news release, "14 Prime hospitals in California knowingly submitted false claims to Medicare by admitting patients who required only less costly, outpatient care and by billing for more expensive patient diagnoses than the patients had (a practice known as 'up-coding')."[5] The settlement resolved numerous allegations that Prime engaged in upcoding from 2006 through 2014 by falsifying information concerning patient diagnoses, including complications and comorbidities, in order to increase Medicare reimbursement.

In 2019, there was a jump in the number of settlements involving allegations of upcoding, including one enforcement action in Illinois against multiple healthcare providers of physical therapy and skilled nursing services accused of increasing their Medicare reimbursements through upcoding. This resulted in multiple

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settlements equaling nearly $9.7 million.[6]

Another prominent example of upcoding is related to billing code modifiers. Namely, for more than a decade the OIG's website has posted notices of physicians and hospital systems paying back millions of dollars for the use of E&M modifier 25. Modifier 25 is used to indicate that a significant and separately identifiable E&M service was provided on the same day as a minor surgical procedure. While additional payment is rendered for a separate E&M service provided on the same day as a procedure, upcoding occurs if a provider uses Modifier 25 to claim payment for an E&M service when the patient care rendered was *not* significant, separately identifiable, and above and beyond the care usually associated with the procedure.

Finally, in addition to its applicability to providers, the upcoding theory of liability has been applied to medical device manufacturers, which do not directly bill federal healthcare programs. For example, in a February 2014 settlement, a Washington-based medical device manufacturer paid more than $5 million to resolve upcoding allegations that it misled healthcare providers about how to bill federal healthcare programs for a procedure using a device manufactured by the company.[7] The manufacturer's medical device could be implanted through two procedures, one of which was a more invasive and thus more expensive approach. In promoting its device, the device manufacturer allegedly advised providers to bill for this more expensive procedure, improperly causing the government to pay more than needed.

The Need to Strengthen Coding Compliance Programs

The OIG has given ongoing guidance regarding the prevention of fraud, waste, and abuse. The core and foundational series of documents from the OIG to help the healthcare industry were published from 1998 through 2008—the Compliance Program Guidance documents.[8] These OIG guidance documents were designed to promote the adoption and implementation of voluntary compliance programs within the healthcare industry. They are specifically directed at various segments of the healthcare industry, including physician practices, nursing homes, hospitals, and third-party billers.

The OIG guidance documents recommend third-party billers develop robust policies that outline a step-by-step process that a coder should take, particularly where documentation is missing or insufficient.[9] The OIG guidance documents provide that billing company policies should ensure that coding and billing are based on medical record documentation, placing particular emphasis on appropriate diagnosis codes and diagnosis-related group (DRG) coding. While companies that do not provide coding services may not need to dedicate the same portion of the compliance program to coding, it is nonetheless important for companies to take steps to ensure that proper coding practices are being used to avoid becoming unwilling participants in a fraudulent coding scheme.

Medical Necessity under the False Claims Act

As discussed in other chapters in this book, to prevail on an FCA claim, a plaintiff must prove the following occurred: (1) a false statement, (2) made with the requisite scienter (or knowledge that it was false), (3) that was material, causing (4) the government to pay out money.[10]

Cases involving allegations of providing services that were not medically necessary typically fall under the "false certification" theory of FCA liability. Under the false certification theory, a defendant faces liability not for an express falsehood, but for falsely asserting that it has complied with a statute or regulatory requirement by submitting a claim.[11] In other words, when "a defendant makes representations in submitting a claim but omits its violations of statutory, regulatory, or contractual requirements," such as failing to report that the good or

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service provided was not medically necessary; "those omissions can be a basis for liability if they render the defendant's representations misleading with respect to the goods or services provided."[12]

"Medical Necessity" Defined

Under Medicare, the concept of "medical necessity" is derived from statute: "No payment may be made . . . for any expenses incurred for items or services, which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[13] Medicare attempts to simplify the definition of medical necessity on its website: "Health care services or supplies needed to diagnose or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine."[14] When seeking reimbursement, the CMS-1500 form requires, in part, the billing entity certify that "the services on this form were medically necessary."[15]

Likewise, medical necessity is a federal and state law requirement under Medicaid.[16][17] In a billing context, medical necessity in layman's terms simply means seeking payment for providing services that were necessary to treat or improve the patient. A false claim for lack of medical necessity can also mean, however, inflating the volume or value of services provided, such as inpatient rather than outpatient care. For more information on this, see the "Outpatient Observations vs. Inpatient Admissions" section of this chapter.

The difficulty of both defending and prosecuting medical necessity FCA cases lies in the fact that they are not always subject to an objective standard. FCA cases involving objective standards can be more clean-cut than their subjective counterparts (e.g., if a record is falsified, the act either did or did not occur). There would not be a subjective professional opinion on the benefits of falsifying records.

In contrast, medical necessity determinations in FCA cases are based on subjective clinical standards made by professionals. In the past, courts have been deferent to medical determinations made by medical professionals, but recent case law suggests there are limits to that deference. The initial decision to provide medically necessary treatment would presumably be made by a healthcare professional, such as a treating or reviewing physician. In addition to using their experience and medical publications, the physician and/or billing department would consult the *Medicare Benefits Policy Manual*, national and local coverage determinations, and state regulations and provider manuals to reach a determination on the proper treatment. However, healthcare professionals can —and often do—disagree about the course of treatment. Wherever possible, prosecutors attempt to overcome such expert disagreements by investigating other avenues of misconduct to tie to the provider's determinations of medical necessity.

It is helpful to review recent examples of medical necessity FCA cases to understand the concepts in context before turning to best practices. For reading ease, the term "government" here includes both the federal government and relators who stand on behalf of the government.

Recent Examples of Medical Necessity in FCA Actions

In 2014, an integrated cancer provider was alleged to have improperly billed for a procedure that measured the exit dose of radiation for cancer patients.[18] Notably, the government's argument was not that the patients did not need the procedure, but rather that the procedure in some circumstances did not serve a medically necessary purpose because the *providers* were not trained to use the results, and there was often a significant delay between the procedure and the provider reviewing the results. There were also allegations that the equipment had technical failures, which would have purportedly made it impossible to obtain results. This is notable because the prosecution focused on allegations related to provider *conduct* instead of relying on the treating physician's

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judgment. Ultimately, in 2016 the corporation settled the allegations for $35 million.

In a 2015 example, a provider was alleged to have used corporate standing orders to require physicians to order medically unnecessary urine, drug, and genetic testing. The company was also alleged to have provided physicians free urine testing supplies in exchange for referrals in violation of the Anti-Kickback Statute and Stark Law.[19] Here, the government did not need to focus on whether the urine, drug, or genetic testing was medically necessary. Instead, the government could allege that the Anti-Kickback Statute and Stark Law violations were sufficient to taint the provider's determination of medical necessity. In October 2015, the government reached a settlement with the provider to resolve the FCA allegations for $256 million, as well as an agreement to enter into a five-year corporate integrity agreement.

In skilled nursing facility cases, the government has often focused on the medical necessity of services provided during a resident's initial evaluation period, which is used to determine the overall reimbursement rate. For example, a skilled nursing operator was alleged to have system-wide policies to increase the level of services provided to patients during the time period when the Resource Utilization Group (RUG) score was calculated, which would result in higher reimbursement rates. The higher RUG level was irrespective of whether the skilled services were medically necessary. The government included allegations of additional FCA violations, and "based on the company's ability to pay," the allegations were settled for $53.6 million.[20] It should be noted that October 1, 2019, marked the end of the prospective payment system, which focused primarily on RUG scores, and introduced the patient-driven payment model (PDPM), which decreased the focus on the initial evaluation and instead focuses on reimbursement for various conditions.[21]

Whether a difference in medical opinion alone is sufficient to support an FCA claim under "medical necessity" currently has caused a split of authority among the Eleventh, Third, and Ninth circuits. In September 2019, the Eleventh Circuit Court of Appeals held that a Medicare hospice claim cannot be deemed false under the FCA based only on a difference in clinical judgment. Instead, there must be proof of an objective falsehood. The corporation —AseraCare Inc.—was alleged to have submitted false claims for Medicare's hospice benefits on the basis of clinical judgments that the government argued were erroneous. The court explained that "If…all the Government needed to prove falsity in a hospice provider case was one medical expert who reviewed the medical records and disagreed with the certifying physician, hospice providers would be subject to potential FCA liability any time the Government could find a medical expert who disagreed with the certifying physician's clinical judgment."[22] Hence, the court ruled, reasonable differences of opinion among physicians who have reviewed the same medical charts is not enough: "A properly formed and sincerely held clinical judgment is not untrue even if a different physician later contends that the judgment is wrong."[23] Instead, the law simply requires that "physicians exercise their best judgment in light of the facts at hand and that they document their rationale."[24] It is important to note that Medicare hospice benefits are unique in that physicians are tasked with using the medical record and their judgment to predict a patient's life expectancy, instead of a particular course of treatment as in the aforementioned cases.

In early March 2020, the Third Circuit Court of Appeals declined to adopt the *AseraCare* case "objective" falsity standard, which required the government to show both a different clinical opinion *and* proof of an objective falsehood to create a triable dispute of fact. Instead, the Third Circuit held that "a difference of medical opinion is enough evidence to create a triable dispute of fact regarding FCA falsity."[25] In other words, in the Third Circuit, a physician's reasonable opinion is not enough on its own to insulate providers from FCA liability.

And in late March 2020, the Ninth Circuit Court of Appeals weighed in on the issue of medical necessity under the FCA and held that a false certification of medical necessity can support FCA liability.[26] In short, the Ninth

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Circuit expressly rejected the "objective falsity" requirement found in the *AseraCare* case, while also attempting to avoid a circuit split by concluding that its opinion does not conflict with *AseraCare*.[27]

Ultimately, the U.S. Supreme Court will have to resolve the circuit split and determine whether there is an "objective falsity" requirement for medical necessity determinations under the FCA. Regardless, all three cases reject the traditional deference previously shown to physicians' clinical judgments. It is therefore important for providers to incorporate best practices to reduce the risk of FCA liability.

Best Practices

There is no one-size-fits-all approach to reducing the risk of liability under the FCA for medical necessity determinations. However, it is critical for medical records to be timely documented and thoroughly filled out to explain to a payer the rationale for providing the treatment. Some electronic health record platforms ensure the provider or provider management employees are correctly doing so, however it is important to ensure the platforms themselves are following Medicare guidelines. Further, providers should stay up to date with current treatment trends to ensure that they are still acting within commonly accepted medical practices.

Finally, providers must take internal complaints of false claims seriously. The provider and/or the compliance officer should have checklists in place that address what happens when an allegation of a medically unnecessary service (or services) are being made. Further, experienced FCA counsel should be contacted to assist in the investigation to both protect the company and, if necessary, comply with all report and repayment obligations to reduce exposure under the FCA. Ultimately, if the claims are ignored but later substantiated, the provider can be subjected to civil fines, penalties, and criminal prosecution. As shown, the penalties for noncompliance are steep, and can often be avoided by early action.

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