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Claim Certifying Medical Necessity Must Meet Definition of 'Reasonable and Necessary'

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The False Claims Act (FCA) imposes liability on one who, among other things, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." While the FCA does not define what makes a claim "false or fraudulent," courts have held the FCA prohibits both factually false claims (e.g., claims that allegedly misstate the procedures or services rendered) and legally false claims (e.g., claims that falsely certify, either explicitly or implicitly, compliance with applicable statutes, regulations, or contractual provisions).

In several recent cases, relators have alleged violations of the FCA based on allegedly false certifications that services submitted for Medicare and Medicaid reimbursement were medically necessary. Title XVIII of the Social Security Act, which governs Medicare, states that payment shall not be made by Medicare "for any expenses incurred for items or services" that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. §1395y(a)(1)(a). Thus, physicians and medical providers who seek reimbursement under Medicare generally must "certify the necessity of the services and, in some instances, recertify the continued need for those services." 42 C.F.R. 424.10(a).

Health care providers know—and anyone who has encountered a difficult medical decision can likely also attest—that views on the necessity of particular treatment or service can be subjective. Federal district courts have agreed in a number of recent cases, holding that a mere difference of opinion as to the medical necessity of services is not sufficient to establish that a medical necessity determination was objectively false, as required to establish liability under the FCA.

In *United States ex rel. Polukoff v. St. Mark's Hospital et al.*, 895 F.3d 730 (10th Cir., July 9, 2018), however, the U.S. Court of Appeals for the Tenth Circuit

reversed such a decision, denouncing the existence of any "bright-line rule that a medical judgment can never serve as the basis for an FCA claim," and finding that the relator sufficiently alleged both that a physician's representations regarding medical necessity were objectively (and knowingly) false, and that two hospitals who employed the physician acted in at least reckless disregard of that fact in submitting claims for their services related to the procedures. Nevertheless, the Tenth Circuit's decision suggests that alleged FCA violations based on the submission of claims for services that were purportedly not medically necessary may still be subject to dismissal where the complaint lacks reliable indicia that the medical necessity determinations were objectively false.

'Polukoff'

In this qui tam action, a physician filed suit against a fellow physician (a cardiologist) and two hospitals where the cardiologist worked. The relator alleged that the cardiologist violated the FCA by performing and billing federal health care programs for medically unnecessary heart procedures, and alleged that the hospitals were also liable because they billed for hospital services furnished in connection with the procedures despite red flags indicating that the services were unnecessary.

In 2017, the district court granted the defendants' motions to dismiss the complaint. The court found that the complaint failed to satisfy Federal Rule of Civil Procedure 9(b)'s heightened pleading standard as to one of the hospital defendants, and, notably, that the complaint failed to sufficiently allege an FCA violation as to all defendants, because it did not identify any claim that was objectively false. The court reasoned that representations regarding medical necessity of the heart procedures were medical judgments that—as a matter of law—could not be objectively false in the absence of a binding regulation defining the medical necessity of such procedures, such as a national or local coverage determination (of which there was none).

As noted above, the Court of Appeals reversed, finding that the complaint sufficiently alleged that the certifications of medical necessity were objectively false, and that the defendants knowingly submitted these false certifications.

Tenth Circuit's Definition of Medical Necessity

In reaching its conclusion, the Court of Appeals adopted a government argument set forth in the government's amicus brief—the DOJ had declined to intervene in the case—that "[a] Medicare claim is false if it is not reimbursable, and a Medicare claim is not reimbursable if the services provided were not medically necessary." The court's decision then took an unexpected turn: to be reimbursable, it explained, a claim certifying that a procedure is medically necessary must meet the definition of "reasonable and necessary" set forth in CMS's Medicare Program Integrity Manual (MPI), §13.5.1.

That definition is broad and heavily fact-dependent. Among other things, the MPIM looks to whether a procedure is: (1) safe and effective; (2) not experimental or investigational; (3) appropriate, including in duration and frequency, because it is furnished in accordance with accepted standards of medical practice, furnished in a setting appropriate to the patient's medical needs, ordered and furnished by qualified personnel, sufficient to meet but not exceed the patient's needs, and at least as beneficial as other available alternatives.

For the case at hand, the Tenth Circuit referenced allegations that: (1) the cardiologist performed an unusually high number of procedures as compared to other providers; (2) the physician routinely performed a particular cardiac procedure on patients who had not experienced the indicative symptoms set forth in guidelines issued by the American Heart Association and American Stroke Association; (3) other physicians at one of the hospitals had objected to the cardiologist performing the procedures; (4) one of the hospitals eventually audited certain of the procedures and concluded that they were not performed in compliance with the hospital's internal guidelines regarding medical necessity, and took adverse action with respect to the cardiologist's medical staff privileges following the review; and (5) the cardiologist's representations regarding the reason for the procedures were misleadingly tailored so that they would be reimbursable.

The Tenth Circuit acknowledged that a broad definition of "false or fraudulent" might expose physicians (and presumably their employers, as in the case at hand) to

increased liability under the FCA, but stated that "concerns about fair notice and open-ended liability can be effectively addressed through strict enforcement of the [FCA]'s materiality and scienter requirements." This statement may not provide much comfort to defendants in FCA cases, though, at least not prior to discovery. A relator or the government may be able to sufficiently plead materiality by pointing, among other things, to the medical necessity certification requirement under the Medicare conditions of payment. Additionally, under Rule 9(b), scienter may be alleged "generally."

Medical Judgment vs. Objective Falsity

One of the hospital defendants challenged the Tenth Circuit's decision in an unsuccessful petition for rehearing. The hospital argued, among other things, that the MPIM's definition of "reasonable and necessary" is non-binding guidance directed to Medicare contract administrators, not to providers, and that this guidance is not even applicable to Medicaid or other providers. The hospital argued that the court's decision went against settled law and the DOJ's own policy, as announced in the 2018 Brand Memo, that noncompliance with agency guidance documents does not "presumptively or conclusively" establish violations of law in affirmative civil enforcement cases. At oral argument on the motion to dismiss, the government itself described the MPIM as a manual that "does not have the force of law."

On Oct. 29, 2018, the Tenth Circuit denied the petition for rehearing in a cursory three-sentence order. The decision thus leaves open the question of to what extent the MPIM, or other internal Medicare guidance documents, will govern in other medical necessity cases.

Nevertheless, the Tenth Circuit decision does not foreclose arguments that medical necessity cases should be dismissed for failure to plead objective falsity. The Tenth Circuit explained that its sufficiency determination was based on the "specific allegations" outlined above, many of which dovetailed with the MPIM definition. In the absence of indicia of objective falsity like those identified by the court, an FCA complaint that is premised on false certification of medical necessity may still be subject to dismissal. Allegations of objective falsity must also satisfy Rule 9(b)'s heightened pleading standard; general allegations of disagreement or uncertainty regarding necessity may not be sufficient.

Additionally, the kinds of indicia required to sufficiently plead objective falsity may vary depending on the medical judgment at issue, including the level of subjectivity inherent in exercising that judgment. For example, courts may require different—and perhaps greater—indicia of falsity in cases challenging the medical necessity of determinations regarding eligibility for hospice care, or the classification of a patient for inpatient admission versus observation status.

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