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Tenth Circuit Rejects Request for Rehearing in Closely Watched FCA Medical Necessity Case

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In a three-sentence order issued on October 29th, the Tenth Circuit Court of Appeals declined to grant a Request for Rehearing in the closely watched *Polukoff* case. One of the questions raised in the Request was whether, by submitting a claim for reimbursement and certifying the medical necessity of the charged service, providers also certify that the claim meets all of the standards set forth in the Medicare Program Integrity Manual (MPIM). This decision, coupled with the Tenth Circuit panel's decision back in July to revive the relator's FCA claims, has not only left open the question of what standard the Tenth Circuit will follow in False Claims Act (FCA) medical necessity cases, but has also potentially paved the way for future FCA medical necessity claims based on a physician's alleged failure to follow manual provisions, medical society guidelines, and other guidance documents that are not embodied in regulations or a National Coverage Determination (NCD), as well as claims based on hospitals' alleged reckless disregard for whether their claims for inpatient services were related to the physician's allegedly medically unnecessary procedures.

In other words, this decision raises the troubling possibility that a claim for physician services may be "medically unnecessary" and "false" absent any objective criteria, and that hospitals may be liable for submitting claims for inpatient services if they were in "reckless disregard" as to whether physicians complied with subjective sub-regulatory guidance, which does not apply directly to providers and does not have the force of law. Such an outcome contradicts DOJ's expressed intent that guidance documents not be used by DOJ to establish violations of law, as set forth by the Department earlier this year in a memorandum prohibiting DOJ from using noncompliance with guidance documents for that purpose.

In February 2017, the district court originally dismissed the complaint, in part, on the grounds that the relator's FCA claims failed as a matter of law because he had not shown that the defendants "knowingly made an objectively false representation to the government that caused the government to remit payment" for the procedures at issue. (We wrote a detailed post on that decision.) In reaching its decision, the district court found that the representations by the performing physician and billing hospitals that the procedures at issue were medically reasonable and necessary could not be proven to be "objectively false" for purposes of FCA liability because "opinions, medical judgments, and 'conclusions about which reasonable minds may differ cannot be false'" for purposes of an FCA

claim. The district court also commented that "liability may not be premised on subjective interpretations of imprecise statutory language such as 'medically reasonable and necessary.'"

Also important to the district court's decision was the fact that the Medicare program had not issued an NCD that set forth when the procedures at issue would be considered "reasonable and necessary" for purposes of Medicare coverage. And the district court rejected the relator's attempt to rely on medical society guidelines and recommendations as proof that the procedures at issue were not medically necessary, noting that the Medicare program does not require compliance with an industry standard as a prerequisite to payment and that requesting payment for procedures that allegedly did not comply with a particular standard of care does not amount to a fraudulent scheme actionable under the FCA.

Many in the healthcare industry (and the defense bar) were heartened by the district court's decision, as it followed behind a similar result in the *AseraCare* case, where, in April 2016, a district court judge granted summary judgment for the defendant hospice provider, finding that the relator had failed to properly allege an objective falsity (see our *AseraCare* post for more details) in a medical necessity FCA action. Some observers saw the district court's decision in *Polukoff* as a possible sign that other courts would follow the *AseraCare* court (and others) in requiring relators to allege more than a disagreement as to medical necessity in order to properly allege falsity in FCA cases, perhaps signaling a growing consensus across jurisdictions.

Given the district court's decision, including the fact it declined to permit the relator to amend his claims on the grounds that doing so would be futile because he could not allege falsity as a matter of law, the Tenth Circuit Court of Appeal's decision to revive the relator's claim that – in the absence of an applicable NCD – a physician and hospitals could still face possible FCA liability for submitting claims for services that allegedly did not comply with medical society guidelines, was surprising and troubling to some. (In July, Brian Dunphy wrote a post detailing the Tenth Circuit Court of Appeal's decision in this case.)

The Court of Appeals also rejected the district court's application of the "objective falsity" standard and instead articulated a "falsity" standard that is vague and offers little guidance as to how the Court of Appeals interpreted this standard. In particular, the Court of Appeals found that "[i]t is possible for a medical judgment to be 'false or fraudulent' as proscribed by the FCA for at least three reasons":

1. The Tenth Circuit reads the FCA broadly;

2. The fact that an allegedly false statement constitutes a speaker's opinion does not disqualify it from forming the basis of FCA liability; and

3. Claims for medically unnecessary treatment are actionable under the FCA.

In overturning the lower court's decision, the Court of Appeals adopted an argument advanced by DOJ in an amicus brief (which the Department submitted even though it had declined to intervene in the case itself): 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." In the absence of an NCD or LCD, the Court explained, a claim must meet the government's subjective definition of "reasonable and necessary," as found in the MPIM.

As one of the defendants, Intermountain Healthcare, Inc. (IHC), pointed out in its Request for

Rehearing, the MPIM is not binding on providers but instead provides guidance to Medicare administrative contractors developing coverage policies to 'consider a service to be reasonable and necessary' if the procedure is furnished in accordance with accepted standards of medical practice. By declining to reconsider this issue – especially in light of the fact that the government acknowledged at oral argument that the MPIM does not have the force of law and the fact that DOJ issued a memorandum earlier this year prohibiting DOJ from using noncompliance with guidance documents to establish violations of law – the Tenth Circuit Court of Appeals has seemingly left the door open for future FCA relators to assert claims premised on the alleged lack of medical necessity based on failure to comply with medical guidelines or Medicare manual provisions, while at the same leaving defendants with little guidance on how the Tenth Circuit will interpret the "falsity" standard in such cases.

As always, we will continue to monitor this issue and report back on future updates.

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