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HEADLINE: Nursing Homes Face Quality-of-Care Scrutiny under the False Claims Act;
Brief Article

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BODY:

The Federal government has brought a series of civil actions against nursing home operators for alleged violations of the Federal False Claims Act. According to government prosecutors, if a nursing home submits Medicare or Medicaid claims for care the government considers substandard, the claims are false for that reason alone.

However, the government's theory ignores the fact that the detailed Federal statutes and regulations that govern nursing homes, as well as the agencies that enforce them (the "regulatory enforcement scheme"), allow homes that have been found to provide substandard care to continue receiving Medicare and Medicaid payment while they correct their deficiencies. Until recently, most of the cases had settled, and the government's theory had not been addressed in a published court decision. In a recent case, however, a Federal judge refused to grant the defendant facility's motion to dismiss and permitted the government's case to proceed.

Beleagued by intensifying regulatory scrutiny and enforcement, as well as increased liability exposure to civil actions brought by residents or their families for neglect and abuse, nursing home operators also face potential liability under the Federal False Claims Act. Recently, the government has attempted to expand the act's scope of liability to include payment claims by nursing homes participating in the Medicare and Medicaid programs if the government considers the care provided by the nursing homes to be substandard. The government has brought several civil cases based upon this theory and has indicated that it intends to bring more such actions.

Until recently, most of the provider defendants in such lawsuits (none of them large companies) had settled, rather than risk having to pay costly damages and penalties. Thus, this theory of liability had not been subject to a rigorous challenge in court. The government's actions, however, ignore the comprehensive Federal regulations that already

enforce of quality standards in nursing homes.

Of course, long-term care providers can best avoid problems by limiting the opportunities for anyone to make allegations of substandard care in their facilities. Nevertheless, because many nursing home patients have serious, chronic health problems, questions regarding care are bound to arise despite conscientious treatment and could generate additional False Claims Act litigation. Facility owners, therefore, should be prepared to make an appropriate legal response. A False Claims Act action should not have to result in a costly settlement or false claims liability.

Substandard Care and the False Claims Act

The section of the False Claims Act most often relied upon by the Department of Justice in prosecuting actions against healthcare providers states that a person who knowingly presents or causes someone else to present a false or fraudulent claim for payment or approval to the government is liable for that submission. The terms "knowing" and "knowingly" in the statute mean that a person has actual knowledge of the information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of its truth or falsity. The government does not have to prove that the person intended to defraud the government.

When a provider submits a claim to the government for care that allegedly was substandard, the government asserts that the provider has submitted a false claim because the claim is an "implicit certification" of compliance with all Medicare and Medicaid statutes and regulations, including those governing quality of care. The government first advanced this implicit certification theory in the nursing home context in the Tucker House case. [a]

The government alleged that the facility provided grossly inadequate nutrition and wound care to three former residents in violation of Federal regulations. The government then focused on the facility's provider agreement, in which the nursing home acknowledged that submission of a claim constituted a certification that the services for which payment was claimed actually were provided to the identified beneficiary, and that participation in the Medicare or Medicaid program is subject to applicable legal requirements, that is, statutes and regulations.

The facility settled the case by paying \$600,000, and agreed in a broad consent order to ensure future compliance.

The government advanced a similar theory in an Oklahoma case involving a psychiatric provider. [b] The court in that case rejected the defendant's argument that it could not knowingly violate subjective Medicare quality standards, and accepted the implicit certification theory. Since Tucker House, the government has filed several similar nursing home cases, all of which were settled. [c]

In one instance, the government's case appeared to be based upon significantly less serious allegations of substandard care. [d] This development could be an ominous one for long-term care providers, because it may indicate that the government is moving away from its earlier position that only truly egregious or gross negligence or total failures to provide care for which claims were submitted would be prosecuted under the False Claims Act.

The government's position in these cases seems to be an overly aggressive use of the False Claims Act. The act requires that the government prove a false or fraudulent claim for payment, and nothing in existing law establishes that a claim necessarily includes unstated, implied representations concerning compliance with all applicable laws and regulations. This is especially so in long-term care, because the nursing home regulatory enforcement scheme explicitly tolerates noncompliance by requiring only "substantial" rather than total compliance, and, as explained below, allows payment even in some instances where serious violations of regulatory requirements exist.

Noncompliance with quality-of-care requirements may be actionable under the nursing home regulatory enforcement scheme or through direct actions by injured residents, but is not generally a legitimate basis for a claim under the False Claims Act, [e] A false claim would be one that the defendant knowingly submitted for services that were not provided, such as a claim for respiratory or physical therapy services that were needed and ordered but never received by the resident.

No "Implicit" Certification

The certification of compliance is a particularly important issue in health care. The Medicare payment claim form generally contains a statement that the provider is certifying the services listed on the form were medically indicated and necessary for the patient's health and were furnished by the provider or by an employee under the provider's immediate personal supervision. The language of this statement has been used to argue that the provider also implicitly certifies compliance with all Medicare statutes and regulations. Under this theory, submission of a claim for services when Medicare statutes, regulations, or both have been violated alone is sufficient to constitute the submission of a false claim.

However, an express certification that medically necessary care was furnished by the provider does not mean there is an implicit certification of compliance with all applicable statutes and regulations. The implied certification theory has been rejected in several Federal court cases, including some in the healthcare context [f] These courts have found that a False Claims Act case cannot be based solely on a violation of a law, rule, or regulation, without an express false certification of compliance.

One court noted that False Claims Act actions are particularly inappropriate to redress regulatory violations in instances where compliance is not a prerequisite to government funding, and there are administrative and other remedies for regulatory violations. Another court summarized the prior cases as holding that "implied false certification is to be found only in those exceptional circumstances where the claimant's adherence to the relevant statutory or regulatory scheme lies at the core of its agreement with the government, or, in more practical terms, where the government would have refused to pay had it been aware of the claimant's noncompliance. [g]

Nevertheless, certification arguments also have been used to assert that alleged violations of Medicare fraud-and-abuse statutes constitute violations of the False Claims Act, and courts have allowed such actions to proceed. [h] According to one court, however, though a defendant may be liable both for violations of fraud-and-abuse laws and the False Claims Act, a violation of the fraud-and-abuse laws does not amount to a per se violation of the False Claims Act. That decision suggests that for claims to be actionable under the False Claims Act, they must have been paid as a result of the defendant's fraudulent actions and the defendant would not otherwise have been entitled to the money

One Federal appeals court held that violations of fraud-and-abuse laws might be sufficient for False Claims Act liability if payment was "conditioned" on the provider's certification of compliance with those laws. When the case upon which the appeals court ruled was returned to the lower court, the court admitted into evidence a declaration from the acting chief of HCFA that the government does rely on providers' certifications of compliance in making payment and retention-of-payment decisions. The court then held that because the Federal antireferral statutes prohibit both claims and payments for services rendered as a result of prohibited referrals, submission of claims in violation of those statutes was actionable under the False Claims Act. [i]

Recently a Federal district court refused to dismiss a quality-of-care false claims case against a nursing home, based in part on the notion that the defendant facility had implicitly certified that it would comply with the "standard of care as set forth in the regulations and statutes." Although the court acknowledged that the "false certification" theory applies only if the government would have refused to pay if it had known of the noncompliance, the court did not even inquire into whether that situation existed in the case before it. [j]

Under the Federal nursing home enforcement statutes, payment to nursing homes is not conditioned on full compliance or a certification of full compliance, and claims are not "statutorily ineligible for payment" merely because a facility has not achieved compliance with all applicable quality-of-care regulations. Rather, the Medicare statute allows facilities to continue to receive payment for up to six months after deficiencies are cited, whether or not they come into compliance during that time. One reason for such leeway is that nursing homes are both healthcare facility and residence. Cessation of payment could force frail residents to relocate, which can cause serious harm to them.

The Meaning of "False"

Of the elements the government must prove to prosecute an action successfully under the False Claims Act, what constitutes a false or fraudulent claim or activity is the only one that is not defined by the statute, so the courts must interpret what this means. One court stated that the False Claims Act was intended to cover situations in which not only are false claims made, but also the claimant has engaged in fraudulent conduct to induce payment by the government. [k] This vague interpretation does not define fraudulent conduct intended to induce payment.

The government's position in the Oklahoma psychiatric facility case and the nursing home cases is particularly disturbing because it fully presupposes that violations of quality-of-care requirements suffice to establish that false or fraudulent claims have been made. Indeed, the papers submitted by the government in nursing home cases such as Tucker House expressly invoke the nursing home quality-of-care statutes and regulations concerning, for example, nutrition, to allege inadequate care.

In the nursing home context, however, the assumption that regulatory violations establish false claims contradicts the statutory scheme, which allows some noncompliant providers to continue to be paid despite multiple violations of applicable regulations, no matter how severe or widespread—even to the point of causing actual harm to patients' health and safety. Moreover, when a facility has been cited for deficiencies and HCFA or the state (or both) imposes enforcement remedies such as termination from the Medicare and Medicaid programs, a ban on payment for new admissions, or civil monetary penalties, the facility has an opportunity to institute an administrative appeal of that decision. The facility may establish in that administrative appeal that some or all of the cited deficiencies did not exist (for example, by demonstrating that a pressure sore was unavoidable because it resulted from the resident's multiple, chronic, clinical conditions, and not from inadequate care by the facility). The citation of a deficiency is not a legal judgment that it actually occurred; therefore, it cannot be sufficient for the government to establish the existence of a false claim in connection with the specific care provided.

Furthermore, even if a facility has challenged cited deficiencies in an administrative appeal and lost, if the government has allowed the facility to continue receiving payment despite those deficiencies (and the facility has met the statutory and regulatory requirements for continued receipt of payment), then the facility's claims cannot be false. The government cannot establish that the facility knowingly made false certifications of compliance, either express or implied, under such circumstances.

It also is significant that the broad menu of remedies that regulators may impose upon nursing homes for noncompliance with applicable requirements includes civil monetary penalties of up to \$10,000 per day—exactly the penalty the government would propose to duplicate under the False Claims Act. The government has intensified its already-pervasive regulatory enforcement efforts with respect to nursing homes in response to a General Accounting Office report that criticized California nursing homes (and agency action to promote compliance) and a White House initiative to improve nursing home care that includes, among other things, swifter and stiffer penalties. [1] As a result, the number of deficiencies cited and proposed terminations have increased dramatically. The pervasiveness and strength of the existing regulatory enforcement scheme in disciplining noncompliant providers militates against a broad expansion of the False Claims Act into the nursing home quality-of-care arena, not least because it creates the risk of inconsistent enforcement.

This analysis is supported by a 1996 Special Fraud Alert issued by the Office of Inspector General (OIG). The Special Fraud Alert describes certain types of illegal practices by nursing homes (or practitioners who provide services to nursing home residents) that the OIG condemned as "false or fraudulent" claims—precisely the language of the False Claims Act. In the Special Fraud Alert, the OIG did not include pure quality-of-care violations. Rather, the OIG mentioned only claims for services never provided or not provided as claimed, and claims for medically unnecessary services, as the type of claims subject to the Special Fraud Alert. The examples enumerated by the OIG include billing by a speech specialist for spending 20 hours per day with residents, some of whom never had met him and some of whom were deceased at the time he claimed to have seen them; billing by a provider of mobile X-ray services for two

X-rays each time one was taken, by personnel who were not certified to take X-rays; and billing by a podiatrist for performing \$100,000 worth of toenail removals in one year (including 11 such procedures for one resident).

The Special Fraud Alert also lists certain situations that are redflags in billings: "gang visits" by medical professionals who see large numbers of residents in one day; too-frequent routine visits by the same medical professional; overly active presence in the facility by practitioners who have or seek unlimited access to medical records; and questionable documentation of medical necessity.

Although the Special Fraud Alert does not suggest that its list of illegal activities is exhaustive, it indicates that in the OIG's view, false claims involve billing for services that never were provided, were not as represented, or were clearly inappropriate. Although quality-of-care concerns obviously arise from many such scams (eg, the X-rays by noncertified personnel), these are incidental to the OIG's primary focus on bogus billing.

The OIG has independent authority to terminate the provider agreement of a nursing home if the OIG determines, among other things, that the facility has furnished services that fail to meet professionally recognized quality standards for health care. However, termination by the OIG on this basis is likely to occur only in situations where the OIG has learned of fraudulent billing activities by a facility or other providers practicing there and observes substandard care in the course of its fraud investigation. The fact that the Medicare system already provides multiple enforcement agencies and sanctions for substandard care in nursing facilities should militate against extending the False Claims Act to provide additional remedies for conduct that does not constitute knowing submission of false claims for payment.

In addition, nursing homes increasingly are subject to heightened liability for seriously deficient care under state elder abuse-and-neglect statutes. For example, the California Supreme Court decided in March 1999 that a facility whose conduct constituted "reckless neglect" of a resident was liable for attorneys' fees and pain-and-suffering damages under the state elder abuse statute, and could not take advantage of limitations in the statute relating to "professional negligence" claims. [m]

Conclusion

With the long-term care industry facing escalating sanctions for poor care on multiple fronts, the False Claims Act should not be expanded inappropriately into the nursing home quality-of-care arena. The False Claims Act was intended to target those who intentionally are trying to cheat the government by knowingly submitting false claims, not those who are trying to provide appropriate services but fall short. Moreover, the Medicare and Medicaid payment system specifically was designed to accommodate the unique challenges of the nursing home industry by allowing providers to continue to receive payment while they implement measures to correct problems and improve care. Under those circumstances, the nursing homes' claims for payment simply are not false within the meaning of the False Claims Act.

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(a.) *United States v. GMS Management-Tucker, Inc. et al.*, No. 96-1271 (E.D. Pa. 1996).

(b.) *United States ex rel. Aranda v. Community Psychiatric Centers of Oklahoma*, 945 F. Supp. 1485 (W.D. Ok. 1996).

(c.) *United States v. Chester Care*, Civil Action No. 98-CV-139 (E.D. Pa. 1998); *United States v. City of Philadelphia*, Civil Action No. 96-4253 (E.D. Pa. 1998); *United States v. Greenbelt Nursing and Rehabilitation Center*, Civil Action No. AW 98-3113 (D. Md. 1998).

Nursing Homes Face Quality-of-Care Scrutiny under the False Claims Act; Brief Article Healthcare Financial Management January 1, 2001

(d.) Northern Health Facilities, Inc. v. United States, 39 F. Supp. 2d 563, 567, 571 (D. Md. 1998). (The deficiencies cited in the Greenbelt case did not immediately jeopardize the health or safety of residents.)

(e.) See, eg, United States ex rel. Mikes v. Straus, 84 F. Supp. 2d 427 (S.D.N.Y. 1999) (rejecting the notion that False Claims Act liability can be based on alleged failure to meet the standard of care and emphasizing that "the FCA is not a vehicle for regulatory compliance"); Luckey v. Baxter Healthcare Corporation, 2 F. Supp. 2d 1034, 1044-1045 (ND. Ill. 1998) (same).

(f.) United States ex. rel. Hopper v. Anton, 91 F.3d 1261, 1265 (9th Cir. 1996); United States ex rel. Weinberger v. Equifax, Inc., 557F.2d 456 (5th Cir. 1977), cert. denied, 434 U.S. 1035, 98 S.Ct. 768 (1978); United States ex ret Joslin v. Community Health Care of Maryland, 984 F. Supp. 374 (D. Md. 1997) (home health); Luckey, supra, 2 F. Supp. 2d 1034, affirmed, 183 F. 3d 730 (7th Cir. 1999) (laboratory blood plasma tests); United States ax rel. Swafford v. Borgess Medical Center, 98 F. Supp. 2d 822 (W.D. Mich. 2000) (interpretation of ultrasound test); Lum v. Vision Service Plan, 104 F. Supp. 2d 1237 (D.Haw. 2000) (charging \$7 copayment for vision care in violation of law).

(g.) United States ex rel. Mikes, supra, 84 F. Supp. 2d at 435.

(h.) United States ex ret. Roy v. Anthony, 914 F. Supp 1504 (S.D. Ohio, 1994); United States ex rel. Pogue v. American Healthcorp, Inc., 914 F. Supp. 1507 (M.D. Tennessee, 1996).

(i.) United States ret. Thompson v. Columbia/HCA Healthcare Corp., 20 F. Supp. 2d (S.D. Tex. 1998), on remand from 125 F.3d 899 (5th Cir. 1997), vacating in part and remanding, 938 F. Supp. 399 (S.D. Tex. 1996).

(j.) United States v. NHC Healthcare Corp., 115 F. Supp. 2d 1149 (W.D. Mo. 2000). The court noted that, in the context of the motion to dismiss, it was required to give the benefit of any doubt to the government, which might have a difficult time actually proving its case. The court also mentioned the controversy over whether this use of the False Claims Act is proper, but left that issue for the appellate courts, Congress, or the relevant agencies to decide.

(k.) Pogue, supra, 914 F. Supp. at 1511.

(l.) See, eg. 64 Fed. Reg. 13354 (March 18, 1999) (publication of final regulations giving the Secretary of the Department of Health and Human Services expanded civil monetary penalty options and eliminating the maximum notification period for imposition of remedies); Robert Pear, "U.S. Toughens Enforcement of Nursing Home Standards," New York Times, December 4, 2000, at A21.

(m.) Delaney v. Baker, 20 Cal. 4th 23 (1999).

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