Criminal enforcement liability: Quality of care, medical necessity, and reasonableness of health care services

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The result of recent civil and criminal fraud enforcement actions has raised the stakes for business organizations related to the quality of care, medical necessity, and reasonableness of providing health care services. The involvement of federal and state law enforcement in pursuing "quality of care," "medical necessity," and "reasonableness" prosecutions requires health care business organizations to more particularly address compliance issues related to the type of care and treatment they provide. The oversight of the quality of care, medical necessity, and reasonableness of health care services is nothing new for these organizations. However, the involvement of the law enforcement community with these issues elevates the need for this oversight and likely requires different methods to address this growing risk for health care organizations.

These developments present challenges because decisions about the quality of care, medical necessity, and reasonableness of care are made on a diffuse basis in most health care organizations, primarily by practicing physicians. (See 42 U.S.C. § 1395 and corresponding case law.) The historical overview of these initial physician determinations has typically been made by Medicare and Medicaid contractors who process claims for reimbursement. (See 54 Fed. Reg. at 4305.) A further review is undertaken at the hospital level through its own utilization review mechanisms in conjunction with quality improvement organizations (QIO), formerly known as peer review organizations. (See 42 U.S.C. § 1320c-5.) These determinations about the quality of care, medical necessity, and reasonableness of health care services, however, have apparently proved to be insufficient to deter criminal and civil enforcement actions by the Department of Justice, the Attorneys General, the Medicaid Fraud Control Units of the different states, and the Office of Inspector General of Health and Human Services.

Furthermore, the advent of "whistleblower suits" based on the quality of care, medical necessity, and reasonableness of health care services, under the United States False Claims Act, has had a profound affect on federal and state enforcement agendas. The legacy of enforcement actions commenced in the nursing home industry. The enforcement actions and case law involving nursing homes, which we have seen over the years, focused on long-term care services or the abdication of those services, which in turn raised the specter of "worthless" services. The courts have found that the provision of worthless services by health care providers could be a basis for False Claims Act liability. The underlying theory has been that the worthless services are analogous to services which have not been provided or that the services were so neglectful as to constitute no care at all. Accordingly, a claim for such worthless services can be considered a false or fraudulent claim under the False Claims Act.

The enforcement actions which have been brought against the hospital and physician segments of the health care industry have been based on a "deficient or worthless service" theory of liability or that the services were not "medical necessary or reasonable." There is a statutory provision under the Medicare and Medicaid programs which specifically excludes from coverage any items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury. [See 42 U.S.C. § 1395y(a)(1)(A) (Medicare) and 42 U.S.C. § 1396a (Medicaid)] This basis of liability has proven more actionable under criminal and civil fraud theories than the quality-of-care basis of liability which developed in the nursing home industry. The reason for this alternative theory of liability, with its statutory underpinnings, is that the standard for liability for quality-of-care actions under the False Claims Act is a rather difficult standard for relators and/or the Department of Justice to establish. The leading decision addressing quality-of-care allegations against a physician group practice stated the following:

> The False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations – but rather only those regulations that are a precondition to payment – and to construe

the impliedly false certification theory in an expansive fashion would improperly broaden the Act's reach. Moreover, a limited application of implied certification in the health care field reconciles, on the one hand, the need to enforce the Medicare statute with, on the other hand, the active role actors outside the Federal Government play in assuring that appropriate standards of medical care are met. Interests of federalism counsel that the regulation of health and safety matters is primarily, and historically, a matter of local concern.

See U.S. ex rel. *Mikes v. Strauss*, 274 F.3d 687, 699-700 (2d Cir. 2001)]

The Court in *Mikes* went on to say that permitting qui tam plaintiffs to assert that defendant's quality of care failed to meet medical standards would promote federalization of medical malpractice, as the Federal Government or the qui tam relator would replace the aggrieved patient as plaintiff." Id. at 700. The Court of Appeals went on to observe that "the courts are not the best forum to resolve medical issues concerning levels of care. State, local or private medical agencies, boards and societies are better suited to mentor quality of care issues." Id.

The *Mikes* decision and another decision involving a nursing home defendant, *U.S. v. NHC Healthcare Corp.* [115 F. Supp. 2d 1149 (W.D. Ma. 2000)] both concluded that the False Claims Act "may properly be invoked if a defendant's services are so deficient as to be worthless." However, the courts also agreed the False Claims Act should not be used to call into question a health care provider's judgment regarding a specific course of treatment. Thus, these courts have limited the False Claims Act from becoming a federal malpractice statute. [See U.S. ex rel. *Phillips et al. v Permian Residential Care Center,* 376 F. Supp. 2d 879 (W.D. Tex. 2005)]

Quality of care, medical necessity, and reasonableness of health care services has, nevertheless, become a growing basis for whistleblower claims under the False Claims Act. A number of cases that have been both reported and filed and under seal are currently being investigated by law enforcement. This places hospitals, as well as physicians, in a vulnerable position and at risk for being named a defendant against these types of allegations. A physician typically makes the initial quality-of-care or medical necessity decision in the hospital setting, yet the hospital is accountable for this physician's decision and vicariously liable for the care and treatment of patients in its facility. The growing basis for whistleblower claims places the hospital in the untenable position of having to more closely monitor the quality of care, medical necessity, and reasonableness of physician services, without necessarily having the type of control over the physician medical staff necessary to effectively monitor those services.

A number of cases involving both criminal and civil fraud enforcement have highlighted the risks for health care facilities for quality of care, medical necessity, and reasonableness of services. The United Memorial Hospital case involved the criminal prosecution and conviction of a medical staff physician, the physician chief of the medical staff, the physician chief of emergency medicine, and the chief executive officer of the hospital, as well as a criminal conviction of the corporate hospital entity itself. This case is likely the most egregious example of the consequences of failure to address quality of care, medical necessity, and reasonableness issues in the physician/hospital setting.

The Redding Hospital case in California a few years ago is another case which involved allegations of over-utilization and lack of medical necessity and reasonableness for cardiac stent procedures in the operating room of the hospital. These allegations resulted in administrative sanctions and enforcement actions against individual physicians and the hospital. These types of cases are now being investigated and pursued by whistleblowers and the Department of Justice and Attorneys General as the basis for False Claims Act liability, with varying levels of allegations involving the quality of care, medical necessity, and reasonableness of care. Accordingly, individuals and organizations are busy defending themselves against allegations based on these issues in criminal and civil enforcement actions. A more thorough discussion of the allegations and evidence involved in these cases is outside the scope of this article, but will be discussed at future HCCA Compliance Conferences.

Some warning signals have already been identified and lessons learned from the cases that have arisen over the last several years. The following would appear to be some significant warnings:

- Medical staff physician's privileges restricted at other hospitals
- Complaints from nursing, operating room, and medical staff
- Quantity of patients and explosive growth of practice
- Negligent credentialing and peer review
- Cloned medical records: inadequate history and physicals; diagnosis inconsistent with treatment and/or treatment regardless of medical necessity or reasonableness
- History of malpractice complaints and related complications
- Evidence of financial motivation superceding quality-of-care and medical necessity considerations
- Conflicts of interest compromising organizational governance and compliance activities for the organization

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The lessons learned from cases thus far are:

- Don't be afraid to "know which way the wind is blowing" when you see the warning signals.
- Investigate whenever it appears there may have been a pattern of billing for deficient and/or unnecessary medical services. If the medical necessity is unclear, do not bill for the service and make restitution where necessary.
- Do not tolerate conflicts of interest in organizational governance and in addressing compliance matters, especially those related to "quality of care" matters.
- Given the law on collective corporate responsibility and deliberate ignorance under the False Claims Act, take little comfort in the fact that specific, high-level hospital officials didn't know about the pattern of billing for unnecessary medical services.

The failure of a hospital, or other health care organization, to effectively audit and monitor quality of care, medical necessity, and reasonableness of services will surely result in potential liability, given the current enforcement environment.

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