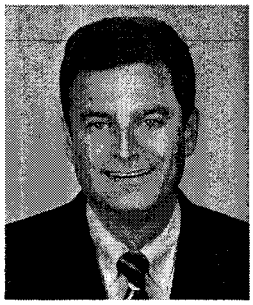
BNA Insights

Continued Focus on Medical Necessity of Interventional Cardiology Procedures: Reactive and Proactive Strategies for Hospitals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On June 4, cardiologist Dr. Sandesh Patil pleaded guilty to charges that he made false statements by overstating the severity of patients' illnesses to receive reimbursement for placing stents, a procedure performed to clear blockage in the arteries.[1] Dr. Patil was sentenced to 30 months in prison, and the hospital where he performed the procedures, St. Joseph's Hospital in London, Ky., faces lawsuits filed by hundreds of former patients alleging that the hospital conspired with Dr. Patil and other cardiologists to perform these costly, but unnecessary procedures. While Dr. Patil is the first cardiologist in Kentucky to be federally prosecuted for fraud related to cardiac procedures, he is the third physician nationwide.

The Patil case is part of a continued and growing trend, from recovery audit contractors to the Department of Justice (DOJ) and the Department of Health and Human Services, Office of Inspector General (OIG), and of course whistleblowers, in which interested parties are voicing concerns about the overuse or misuse of medical tests and procedures. Interventional cardiology procedures in particular have garnered significant attention, evidenced by an increase in the number of investigations, qui tam actions, and overall scrutiny of medical necessity of these procedures.[2]

Recent data and media attention are fueling this focus on medical necessity. In a 2011 study published in the Journal of the American Medical Association, researchers reported that among a sample of patients who received an implantable cardioverter-defibrillator, or ICD, 22.5 percent did not meet evidence-based criteria for the procedure.[3] And, in the second quarter of fiscal year 2013, recovery audit contractors collected $626.5 million from providers, with medical necessity of cardiovascular procedures listed as the top issue in

[1] *See* Press Release, U.S. Attorney's Office for the Eastern District of Kentucky, London Physician Pleads Guilty to Health Care Fraud Charges in First Case of its Kind in Kentucky (June 5, 2013), *available at* http://www.justice.gov/usao/kye/news/2013/2013-06-05-patil.html.

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[2] The focus on medical necessity will not end with interventional cardiology procedures. According to a recent OIG report on spinal devices supplied by physician-owned distributors (PODs), surgeons performed more spinal surgeries at hospitals that purchased from PODs than those that did not purchase from PODs, Office of Inspector General, Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use (October 2013). Following this report, legislators have called for increased scrutiny of procedures performed using medical devices supplied by PODs. *See* Press Release, Sen. Charles Grassley, Senators: Report Confirms Financial Incentives of Physician Owned Distributorships Leads to Increased Surgeries (Oct. 24, 2013), *available at* http://www.grassley.senate.gov/news/Article.cfm?customel_dataPageID_1502=47259.

[3] Sana M. Al-Khatib, et al., *Non-Evidence-Based ICD Implantations in the United States*, 305 J. Am. Med. Ass'n. 43 (2011).

three of the four regions.[4] In addition, profiles of patients who suffered negative outcomes from procedures later deemed unnecessary capture public attention and raise awareness to the issue.[5]

Notwithstanding these stories and statistics, not all physicians and hospitals subject to scrutiny are engaged in fraudulent activity. There is a vast difference between an alternative or even negligent standard of care and a practice that rises to the level of fraud. Those who have been accused, however, draw attention to the industry, raise the level of awareness physicians and hospitals must have of the government's continued enforcement of medical necessity standards, and make them ask how they can guard against potential liability.

Medical Necessity of Interventional Cardiology Procedures

The first investigation related to medically necessary procedures that received nationwide attention was the government's investigation of the cardiology program at Redding Medical Center in California. A qui tam complaint was filed in 2002 by a former patient, Father John Corapi, and his friend Joseph Zerga, followed three days later by a separate qui tam complaint filed by a Redding internist, Dr. Patrick Campbell. The relators alleged that hundreds of unnecessary invasive cardiac procedures and surgeries had been performed by cardiologists at Redding over a period of five years. In 2003, Redding's parent health system paid $54 million to resolve the allegations, and paid another $5.5 million in 2005 following final accounting and data reconciliation. The four physicians accused of performing the unnecessary procedures agreed to pay $32.5 million to settle the allegations and avoid potential criminal liability. Two of the physicians also agreed to never again perform cardiology procedures on Medicare, Medicaid or TRICARE patients.

Also in 2002, a Chicago cardiologist was sentenced to 151 months in prison and ordered to pay over $14 million in restitution for performing unnecessary cardiology procedures on more than 750 patients that were alleged to have resulted in two patient deaths. The cardiologist was one of four physicians, a vice president, and two management companies associated with now bankrupt Edgewater Medical Center that pleaded guilty to federal criminal charges related to medically unnecessary tests, procedures, and admissions and the payment of kickbacks to induce patient referrals.

Since Redding and Edgewater, the DOJ has announced several cases focused on interventional cardiology procedures and percutaneous coronary intervention. In 2009, Dr. Mehmood Patel, a cardiologist in Lafayette, La., was convicted of 51 counts of fraud for performing medically unnecessary coronary procedures involving stents, balloons and other treatments. Dr. Patel was sentenced to 10 years in federal prison and the sentence was upheld in August 2012. In addition, two hospitals where Dr. Patel performed these procedures were subjected to investigations under the False Claims Act (FCA)[6] prompted by a qui tam complaint filed by Dr. Christopher Mallavarapu, a cardiologist and former colleague of Dr. Patel. The FCA cases were based on allegations that the hospitals knew that Dr. Patel was performing medically unnecessary procedures at their facilities. To settle the allegations, the hospitals agreed to pay $1.9 million and $3.8 million, respectively, and one entered into a corporate integrity agreement (CIA) with the OIG.

In 2010, St. Joseph Medical Center in Towson, Md. (SJMC) entered into a $22 million settlement and signed a CIA to resolve the DOJ's allegations of a decade-long kickback arrangement whereby SJMC allegedly issued payments above fair market value pursuant to arrangements with MidAtlantic Cardiovascular Associates (MACVA), a cardiology group, in return for referrals of cardiovascular procedures. The settlement also resolved allegations that SJMC had received payments for medically unnecessary stents performed by Dr. Mark Midei, a former MACVA partner who was later employed by SJMC.[7] The complaint was filed by three cardiac surgeons who practiced at SJMC.

Yet another investigation of medically unnecessary stent procedures resulted in the 2011 indictment of Dr. John R. McLean, who held privileges at Peninsula Regional Medical Center (PRMC) in Salisbury, Md. Dr. McLean was convicted for performing more than 100 unnecessary stenting procedures. He was sentenced to eight years in federal prison and forced to pay $579,000 in restitution. PRMC paid $1.8 million and signed a CIA to settle FCA allegations that its senior medical staff failed to investigate the complaints of staff in the cardiac catheterization laboratory regarding medically unnecessary procedures performed by Dr. McLean.

More recently, an Ohio hospital and physician group, agreed to pay $4.4 million to resolve allegations that cardiologists placed stents and performed angioplasties on patients with insufficient occlusion to require these particular procedures. The hospital was alleged to have submitted claims for these medically unnecessary procedures. The matter was initiated by a former manager of the hospital's cath lab. And in Michigan, a hospital and physician group paid $4 million to settle a suit brought by a Michigan cardiologist alleging that they performed medically unnecessary procedures, including invasive catheterizations and peripheral stents. In that case, the government determined that nearly three-quarters of the patients who underwent invasive catheterizations had no significant blockages.

Medical Necessity Standards and Liability

Medicare prohibits payment for items and services that are not reasonable and necessary for diagnosis and treatment of an illness or injury.[8] Medical necessity determinations are complex—while physicians order services they believe appropriate for their patients, physicians also are expected to take into account the various

[4] Medicare Fee for Service National Recovery Audit Program, Quarterly Newsletter (March 31, 2013), *available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Recovery-Audit-Program/Downloads/Medicare-FFS-Recovery-Audit-Program-2nd-Qtr2013.pdf.

[5] *See, e.g.*, Peter Eisler and Barbara Hansen, *Doctors Perform Thousands of Unnecessary Surgeries*, USA Today, June 20, 2013.

[6] 31 U.S.C. §§ 3729-3733.

[7] Press Release, Department of Justice, St. Joseph Medical Center to Resolve False Claims Act Allegations (Nov. 9, 2010), *available at* http://www.justice.gov/opa/pr/2010/November/10-civ-1271.html.

[8] 42 U.S.C. § 1395y(a)(1)(A).

  HLR ISSN 1064-2137

standards of government and private payers as to what is deemed medically necessary.[9] For Medicare, medical necessity standards for particular services also are promulgated by the Centers for Medicare & Medicaid Services (CMS) in national coverage decisions, or by local Medicare contractors in local coverage determinations. Therefore, medical necessity standards are dispersed throughout numerous regulations and transmittals, are subject to change, and may vary by region due to contractor discretion.[10] However, determining whether an item or service is reasonable and necessary is ultimately a medical decision based on factors such as experience, available data and the patient's medical history, expert opinion and consultations with other medical professionals.

Notwithstanding this complexity, medical necessity of procedures is an issue where the government has sought to impose liability not only on physicians, but also on the hospitals where the procedures were performed based on the theory that the hospital knew or should have known unnecessary procedures were being performed. As illustrated by recent government investigations, physicians performing medically unnecessary procedures face criminal prosecution and the hospitals where the procedures take place are at risk based on allegations that the facilities defrauded government health care programs. All of the hospital cases to date have settled based on civil liability. Potential FCA damages include the amounts of Part A and Part B claims for medically unnecessary procedures submitted to Medicare, Medicaid, or TRICARE, triple damages, and penalties for each claim submitted. In addition, the OIG often seeks to impose a CIA on the facility where the procedures were performed.

Challenges of Medical Necessity Enforcement

These recent cases have highlighted a number of challenges regarding the government's interpretation and application of medical necessity standards. First, by initiating an investigation or enforcement action on the basis of medical necessity, the government is effectively placing itself in a position to question the medical judgment of a physician. And, even where the government has an expert, that expert is reviewing cases—through medical records and films—without the benefit of knowing the patient or the patient's entire medical history. Given the laws and regulations in place to protect a physician's independent medical judgment from certain external influences,[11] it would seem equally problematic that a physician's medical judgment could be compromised by a fear of being subjected to significant liability should the physician disagree as to what services are medically necessary.

Second, a claim submitted for a medically unnecessary procedure is not necessarily a false claim for purposes of liability under the FCA. The government still has the burden of proving, at a minimum, that: (1) the facility presented or caused to be presented, a claim for payment or approval to the government; (2) the claim was false or fraudulent; and (3) the facility had actual knowledge or deliberately ignored information or was reckless in not knowing it was false or fraudulent.[12] This is especially important for hospitals facing potential liability under the FCA for services performed by voluntary medical staff physicians—while the hospital may have submitted claims and provided ancillary services, the hospital did not likely diagnose, exercise medical judgment, order or perform the services alleged to be medically unnecessary. The hospital submits claims for services that were ordered and provided by qualified physicians and may not have any knowledge that the services were not medically necessary.

In addition, the concept of medical necessity has been characterized by some hospitals and physicians as a clinically artificial standard because physicians often are confronted with a wide range of acceptable, evidence-based diagnosis and treatment options, not a set of options that either are clearly appropriate or clearly inappropriate. Patients would not be inclined to seek a second opinion but for the understanding that two physicians, each exercising his or her best medical judgment, could arrive at different conclusions as to an acceptable course of testing or treatment. Significant regional differences in health care practices and spending also have been noted.[13] For these reasons, courts have been reluctant historically to second guess the medical judgment of a physician in FCA cases, or to allow the FCA to become a tool for quality of care and malpractice claims.[14] With opportunity for a reasonable difference of opinion at the point of care, hospitals are placed in a challenging position when it is alleged that they knew or should have known that a service was not medically necessary.

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[9] *See* OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987, 8992 (Feb. 23, 1998) (providers may not bill for services that do not meet "appropriate medical necessity standards" for government and private health care plans).

[10] Additionally, in some instances, courts have determined that Medicare contractors were misinterpreting regulations and applying inappropriate standards for medical necessity determinations. The U.S. District Court for the District of Vermont approved recently a settlement whereby CMS agreed to implement measures to clarify existing program guidance on Medicare coverage for skilled nursing and therapy care after the court determined that Medicare contractors were applying inappropriate standards in claims determinations. *Jimmo v. Sebelius*, No. 5:11-CV-17-CR (D. Vt., *settlement approved* Jan. 24, 2013).

[11] One example is the government's regulation and enforcement of pharmaceutical and medical device labeling and promotion.

[12] 31 U.S.C. §§ 3729(a)(1)(A), (b).

[13] *See The Overuse, Underuse, and Misuse of Health Care: Hearing Before the S. Comm. on Finance*, 110 Cong. 6 (2008) (statement of Peter R. Orszag, director, Congressional Budget Office) (noting geographic variation in health care spending that is not necessarily correlated with quality of care or health outcomes); *see also* Dan D. Matlock, et al., *Regional Variations in Physicians' Attitudes and Recommendations Surrounding Implantable Cardioverter-Defibrillators*, 17 J. Cardiac Failure 318 (2011) (study found that physicians in regions with high rates of ICD use were more likely to recommend ICDs for patients who may receive limited benefit).

[14] In *United States ex rel. Mikes v. Strauss*, the Second Circuit cautioned against courts stepping "outside their primary area of competence" and applying qualitative standards to measure the efficacy of a chosen procedure. 274 F.3d 687, 702 (2d Cir. 2001) (stating further that standards of care are "best enforced by those professionals most versed in the nuances of providing adequate health care").

Government's Theory as to Hospital Liability

Yet, the steady stream of recent medical necessity enforcement efforts demonstrates that these challenges have not deterred whistleblowers and the government from pursuing hospitals under the FCA for allegations related to medically unnecessary services. In most of the cases mentioned above, the government seems to have relied on the "known or should have known" theory for establishing the hospital's FCA liability for medically unnecessary procedures, supported in many instances by relators with clinical expertise. Most of the relators practiced alongside or in the same specialty as the physician(s) alleged to have provided the unnecessary procedures. These relators often are in a position to lend their clinical expertise to the government arguing for particular standards of care for the setting and region, and to assist the government in devising theories as to how the hospital did detect or should have been able to detect patterns of medically unnecessary procedures. The government also may engage outside experts to review medical records and literature and render an opinion as to when a test or treatment is outside the standard of care. In sum, the government is accumulating knowledge to prosecute these cases and deliver a more compelling argument as to why the medical judgment of a physician is subject to scrutiny, particularly in the area of interventional cardiology.

Reactive and Proactive Strategies for Mitigating Potential Liability

Hospitals faced with allegations of medically unnecessary procedures have a number of potential defenses. In the case of interventional cardiology procedures, well-intentioned, skilled cardiologists may have widely varied opinions regarding degree of stenosis and appropriate treatment decisions.[15] A hospital may engage its own outside expert to review the medical records at issue and present evidence that the treatment was consistent with the standard of care. Moreover, there are several key pieces of evidence that a hospital may proffer to demonstrate that, even if the procedures were not medically necessary, it did not act with recklessness or have actual or constructive knowledge that the procedures were not medically necessary. This evidence includes: (1) strong credentialing and privileging processes; (2) addressing complaints or reports of unsupported or excessive procedures; (3) peer review process in place; and (4) data analysis and review to identify outliers, including physician and facility data.

In addition to these reactive strategies, facilities may guard against future FCA allegations regarding medical necessity with proactive strategies such as instituting appropriate checks and balances to assess physician qualifications for medical staff membership and credentials to perform cardiac interventional procedures. Both the initial credentialing of medical staff and regular rescreening through a credentialing renewal process are important processes to have in place and require meaningful review. Perfunctory reviews conducted by credentialing staff should be avoided in favor of credentialing committee review of quality indicators. In addition, peer review of outcomes should be performed regularly and in conjunction with other quality and compliance initiatives, such as the analysis of complications, mortality and morbidity data for outliers and patterns or trends that deviate from the standard of care. While the prior review process historically has been a physician-led process, hospitals should assess their current review processes to ensure an appropriate level of review is being performed, critical follow-up is taking place, and information and possible trends are being shared with legal and compliance personnel. Finally, a facility needs to have a reporting mechanism in place to encourage potential whistleblowers to report up through the organization so that concerns regarding medical necessity of procedures not only are heard, but can be immediately addressed by the facility. And hospitals should ensure medical staff bylaws are written in a way that will allow reviews to be conducted. Prompt and appropriate action in response to complaints or reports of unsupported or excessive procedures is critical.

Conclusion

The recent case of Dr. Patil indicates that government and whistleblowers will continue to challenge the medical necessity of procedures, particularly in the area of interventional cardiology. The government is actively building its toolkit for levying successful challenges—utilizing savvy whistleblowers, medical experts, and available research—to question not only physicians, but the hospitals where they practice. Hospitals should be prepared to engage both proactive and reactive strategies to safeguard against potential liability, including robust peer review programs that operate in conjunction with compliance and quality initiatives.

[15] Rasmus Moer et al., *Variability of Quantitative Coronary Angiography: An Evaluation of On-Site Versus Core Laboratory Analysis*, 19 J. Cardiovascular Imaging 457, 461-63 (2003).

HLR ISSN 1064-2137