

Pre-Publication Draft

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**Physician and Hospital
Quality Reporting Fraud:
Risks and Compliance Methods**

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.1 Introduction

Health care costs are on the rise. Between 1999 and 2008, average annual premiums for employer-sponsored family coverage rose 119%.¹ Faced with exponential growth, the control of health care expenses is at the forefront of political debate. In the private sphere, efforts to contain costs have included hospital and physician reporting and grading initiatives, such as the Leapfrog Group's database², Bridges to Excellence (BTE)³, and the PROMETHEUS Payment® reform project⁴. At the same time, the Federal government has taken steps to limit costs and recoup monies, through increased focus on fraud, waste, and abuse, and new initiatives focused on quality of care. Among these are the Medicare Physician Quality Reporting Initiative (PQRI), the Electronic Prescribing Initiative (E-prescribing), and Maryland's Medicaid Managed Care Organization annual report cards.⁵

However, the focus on quality is not new. In the seminal 2001 work, Crossing The Quality Chasm, the Institute of Medicine (IOM) drew into sharp relief critical problems with the quality of American health care delivery.⁶ The Rand Corporation has also pointed out that Americans only receive approximately fifty-five percent of the health care they ought to.⁷ Given the benefits that increased quality may offer, both in a financial sense and in terms of patient safety, quality improvement in the health care industry is likely to become increasingly more important.

The IOM has defined "quality" in the health care context to mean, in general, "providing patients with appropriate services in a technically competent manner, with good communication, shared decision making, and cultural sensitivity."⁸ In order to provide quality care, the IOM stated that care should generally be safe, timely, effective, efficient, equitable, and patient-centered.⁹ Quality can be broken down into three general areas: structure, process, and outcomes. Structural quality relates to health system

¹ "Employer Health Benefits: 2008 Annual Survey," Kaiser Family Foundation And Health Research & Educational Trust, <http://ehbs.kff.org/pdf/7790.pdf>.

² <http://www.leapfroggroup.org/>.

³ <http://bridgestoexcellence.org/>.

⁴ <http://www.prometheuspayment.org/>.

⁵ See generally, <http://www.cms.hhs.gov/PQRI/>, <http://www.cms.hhs.gov/ERxIncentive/>, and http://www.dhmd.state.md.us/mma/healthchoice/html/mco_report.htm, respectively.

⁶ Crossing the Quality Chasm, Institute of Medicine, c. 2001.

⁷ The First National Report Card on Quality of Health Care in America, RAND Corporation, c. 2006, http://www.rand.org/pubs/research_briefs/2006/RAND_RB9053-2.pdf.

⁸ Quality Chasm, p. 232.

⁹ Quality Chasm, pp. 41-53. These are typically referred to collectively using the acronym "STEEP."

capabilities; process quality addresses the steps taken to deliver care to the patient, and outcomes quality focuses on the patient's health status.¹⁰ However, what is not measured cannot effectively be evaluated. Without concrete data, statements regarding health care quality fall into the realm of assertion, no better than an advertising slogan. A variety of public and private mechanisms have arisen in response to the need to track quality data.

Much of quality reporting, in both the private and public sectors, focuses on measuring outcomes. The majority of state-mandated hospital reporting requires hospitals to report various errors. In the public sector, the Medicare PQRI, the E-prescribing Initiative, and the hospital inpatient and outpatient reporting systems represent the Centers for Medicare and Medicaid Services' (CMS) attempts to address how to measure process quality, these efforts do not actually report or reward quality itself – they merely reward the reporting of how closely a provider adhered to certain quality measures. By contrast, the private sector has been far more innovative. The National Committee for Quality Assurance® (NCQA®) utilizes the Healthcare Effectiveness Data and Information Set (HEDIS®), which collects data from health insurer claims across 71 different measures in 8 different “domains of care.”¹¹ The HEDIS® program reaches back to 1991, and has evolved over time. Similar private efforts have arisen since. Bridges to Excellence® is a series of program modules which incentivize physician adoption of certain behaviors relating to areas such as diabetes, spinal, and cardiac treatment, and adoption and implementation of health information technology based on quality scores.¹² HealthGrades® and the Leapfrog Group provide ratings on health care providers. Health Grades derives the information on which it bases its ratings from outcomes data from public sources, including CMS and state reporting systems.¹³ The Leapfrog Group, on the other hand, derives its data from voluntary reports submitted by hospitals.¹⁴ More recently, the PROMETHEUS Payment® reform project has begun pilot programs to test a model whereby providers are paid for

¹⁰ Quality Chasm, p. 232.

¹¹ <http://www.ncqa.org/tabid/187/Default.aspx>. Measures for 2010 include: childhood immunization status, cervical and colorectal cancer screenings, persistence of beta blocker treatment following a heart attack, fall risk management, annual dental visits, call answer timeliness, ambulatory care, and relative resource use for people with asthma. These measures are grouped into eight domains consisting of: effectiveness of care, access/availability of care, satisfaction with experience of care, use of services, cost of care, health plan descriptive information, health plan stability, and informed health care choices. See, HEDIS 2010 Summary Table of Measures, Product Lines and Changes at http://www.ncqa.org/Portals/0/HEDISQM/HEDIS2010/2010_Measures.pdf. Similar measures are tracked specifically for physicians. See, HEDIS 2010 Summary Table of Measures at http://www.ncqa.org/Portals/0/HEDISQM/HEDIS2010/HEDIS_2010_Physician_Measures.pdf.

¹² <http://bridgestoexcellence.org/Content/ContentDisplay.aspx?ContentID=23>.

¹³ <http://www.healthgrades.com/faq/>.

¹⁴ http://www.leapfroggroup.org/media/file/FactSheet_LeapfrogGroup.pdf. The full version of the 2009 survey can be found at <https://leapfrog.medstat.com/pdf/final.pdf>. At the time of this writing, the 2010 survey is not yet available.

adherence to Evidence-Informed Case Rates® based upon scores of their quality performance.¹⁵

Faced with a diverse and growing array of quality reporting systems, health care providers must understand the broad scope of information that they may be expected to report. For purposes of this chapter, “reporting” occurs when providers make explicit and/or implicit statements regarding quality of care and/or qualifications to render such care which relate to quality. Explicit quality reporting includes a state licensure requirement that hospitals and physicians report adverse outcomes. By contrast, an implicit statement of quality is the simple submission of a CMS-1500 claim form for Medicare payment, since such a submission implies that the entity submitting the claim is able to meet the specific requirements (including quality-oriented requirements) to continue participating in the Medicare program, and which make the care rendered of sufficient quality as to be medically necessary and appropriate.

Given the range of quality reporting initiatives, both optional and mandatory, as well as the breadth of information that is reported, future efforts to reign in health care costs will likely involve a mix of incentivized and required quality reporting programs. With either approach, penalties will be imposed for both fraudulent reporting and failure to report at all. In light of this, it is essential that health care providers and their legal counsel understand how and where errors in reporting may occur. Accordingly, this chapter first examines the current landscape of quality reporting approaches with an eye towards the types of information that must be reported and the methods by which reporting occurs, both at the Federal and state levels, and for both mandatory reporting and optional reporting. It then offers considerations and general guidance for developing a quality reporting compliance strategy, taking into account both physician and institutional reporting requirements.

.2 Quality Measurement and Reporting Progress

Quality reporting occurs using multiple different methods, both at the Federal and state levels. Reporting systems may be mandatory, or may consist of “opt-in” programs, and may also involve explicit and/or implicit statements relating to quality of care or qualifications of the provider that relate to quality. Mandatory reporting systems are any system in which participation is a legal requirement. “Opt-in” reporting systems do not require participation, but may offer benefits or incentives to a healthcare provider, such as increased payment. Both mandatory and “opt-in” reporting systems require explicit statements on quality of care. However, in both types of reporting systems, healthcare providers may also make implicit statements about the quality of care delivered, and/or the ability of the provider in question to deliver quality care. While the penalties for failing to accurately report quality in a system that involves explicit statements are obvious, the pitfalls for improper implicit reporting may not be as apparent.

¹⁵ For more information on Evidence-Informed Case Rates® and POMETHEUS Payment®, see <http://www.bridgestoexcellence.org/Content/ContentDisplay.aspx?ContentID=172>.

.2.1 Mandatory Federal Quality Reporting Efforts

Federal law and Federal health care programs utilize several different approaches by which quality is reported, including: the National Practitioner Data Bank (NPDB), Medicare's enrollment process and conditions of participation (including CMS' authority to expel providers), and efforts by the HHS Office of Inspector General (OIG) to curb Medicare fraud by applying the Federal False Claims Act to instances where providers fail to provide quality health care services and submit claims for such services.

Reporting requirements focus on malpractice actions and other errors, as well as on implicit statements made in connection with and/or by virtue of claims submissions. Failure to report fully and properly may implicate a range of penalties, including loss of Medicare enrollment, civil money penalties (CMPs), and other sanctions.

The NPDB was originally created with the passage of the Health Care Quality Improvement Act of 1986 (HCQIA).¹⁶ The NPDB collects information on physicians, dentists, and other health care practitioners, including information on malpractice payments, licensure actions, and "adverse actions."¹⁷ Reports are collected from hospitals, malpractice insurers, and state licensing boards and generally must be submitted within thirty days of the reported event.¹⁸ Information contained in the NPDB is considered confidential.¹⁹

Failure to report to the NPDB results in different penalties, depending on the entity which fails to report. For example, malpractice insurers which fail to report a malpractice payment are subject to a \$10,000 CMP for each unreported payment.²⁰ By contrast, hospitals which fail to properly report are investigated by HHS and notified of their non-compliance. The hospital may then correct the non-compliance or request a hearing within thirty days of receipt of the notice. If HHS determines that the non-compliance has not been corrected, the immunities granted under HCQIA may be revoked for a period of three years.²¹ Unfortunately, despite the threat of penalties and the benefit of protections, there is some question as to how diligent hospitals are in reporting to the NPDB. Some hospitals avoid reporting by disciplining physicians for a

¹⁶ 42 U.S.C.A. chapter 117, §§ 11101 – 11152.

¹⁷ See generally, 45 CFR part 60. "Adverse actions" include professional review which adversely affects clinical privileges for 30 days or more; accepting a surrender of clinical privileges either while under investigation for possible incompetence or unprofessional conduct, or to avoid an investigation; or when a professional society investigates a physician or dentist. 45 CFR § 60.9.

¹⁸ 45 CFR § 60.5.

¹⁹ 45 CFR § 60.13.

²⁰ 45 CFR § 60.7(c).

²¹ 45 CFR § 60.9(c). Hospitals which report results of professional reviews are granted immunity from liability for damages resulting from the review under 42 U.S.C.A. § 11111(a)(1).

period shorter than thirty days, thereby sidestepping the requirement to report in the first place.²² However, as of 2008, no hospital has ever lost its peer review immunity.²³ The Medicare program also restricts access to Federal Medicare dollars by conditioning enrollment and billing privileges on the reporting of “final adverse actions,” including loss or suspension of licensure, or revocation or suspension of accreditation by an accrediting organization.²⁴ The CMS-855B enrollment application specifically requires the reporting of such information in Section 3.²⁵ Physicians must report such information both upon initial enrollment, and on an ongoing basis within thirty days of the reportable event. Failure to report and/or document this information may result in revocation of a provider’s billing privileges.²⁶ CMS also requires that providers certify compliance with Title XVIII of the Social Security Act, its regulations, Federal and state licensure, certification, and regulatory requirements based on the type of services or supplies furnished; and, that the provider does not employ or contract with individuals who have been excluded from participation in any Federal health care program.²⁷ Similarly, Federal regulations permit CMS to revoke billing privileges if a provider certified as “true” any false or misleading information on the enrollment application, either to be enrolled initially or to maintain enrollment.²⁸

Medicare may also expel providers for breaches of quality. For example, on July 21, 2009, Anaheim General Hospital had its Medicare contract terminated by CMS for failure to comply with Medicare’s conditions of participation for hospitals. The termination was based on a survey conducted by state health officials. The hospital’s malfeasance involved failure to maintain necessary surgery medication, and failure to provide proper oversight of medical staff and procedures, which put patients at risk.²⁹

²² Levine, Alan and Dr. Sidney Wolfe, M.D., “Hospitals Drop the Ball on Physician Oversight,” Public Citizen, May 27, 2009, p. 4. www.citizen.org/documents/1873.pdf.

²³ Levine, Alan and Dr. Sidney Wolfe, M.D., “Hospitals Drop the Ball on Physician Oversight,” Public Citizen, May 27, 2009, p. 8. www.citizen.org/documents/1873.pdf.

²⁴ Also defined to include a Medicare-imposed revocation of billing privileges, a conviction of a Federal or state felony offense within the last ten years prior to enrollment, revalidation, or reenrollment, or an exclusion or disbarment from participation in a Federal or state health care program. 73 FR 69778, 42 CFR § 424.502(a).

²⁵ The same information must be reported in Section 3 of both the CMS-855I for individual physicians and sole proprietorships, and the CMS-855A for Part-A providers. The CMS-855A and CMS-855B also require that owners or managing employees report their own adverse legal actions in Sections 5 and 6 of both forms.

²⁶ 42 CFR § 424.535(a)(9); 42 CFR § 424.516(d)(ii), (iii).

²⁷ 42 CFR § 424.516(a).

²⁸ 42 CFR § 424.535(a)(4). The implication of this language is that, in addition to falsely or misleadingly reporting information on an application, the knowing failure to update such information also constitutes grounds for revocation of billing privileges.

²⁹ “California Hospital Gets the Boot,” *Modern Healthcare*, July 27, 2009, pp. 12-13.

Medicare's conditions of participation for hospitals include numerous requirements relating to quality. For example, hospitals must have a quality assessment and performance improvement program, which is designed to reduce medical errors and improve health outcomes. Hospitals are required to measure, analyze, and track quality indicators, including adverse events. The hospital governing body, medical staff, and administrative officials must ensure that the program continues, that it includes clear expectations for safety, that the program has adequate resources, and that improvement efforts address priorities for improved quality of care and patient safety.³⁰ Hospitals must also inform patients of their rights prior to rendering (or discontinuing) patient care, including a requirement that the hospital establish a grievance submission procedure – for which the hospital's governing body is responsible.³¹ Additionally, hospitals must have an organized medical staff which operates in accordance with bylaws approved by the governing body of the hospital, and which is accountable to the hospital's governing body; the medical staff must also periodically conduct appraisals of its members and examine credentials of candidates for membership.³²

Hospitals must meet these minimum standards of quality if they wish to participate in the Medicare program. While the conditions of participation themselves are not “reporting” per se, as prerequisites for participation in the Medicare program, they are implicit in many “reports” made by hospitals, such as submissions of claims for payment. The conditions of participation further place burdens on the hospital's governing body to effectively monitor these quality-related conditions.

The OIG has taken an interest in hospital and nursing home boards of directors, and has considered imposing liability when it can show that boards have been aware of major quality problems and either ignored them or failed to act sufficiently to resolve them. In response to this problem, the OIG has recommended using “dashboards” to monitor quality performance.³³ “Dashboards” are graphical reports of performance scorecards. The OIG has emphasized use of such programs in roundtable discussions on

³⁰ See generally, 42 C.F.R. § 482.21.

³¹ 42 C.F.R. § 482.13(a). Among the patient's rights are: the right to participate in the development and implementation of a plan of care; the right to make informed decisions regarding their care; the right to formulate advance directives and have the hospital's practitioners comply with those directives; rights to privacy, safety, and confidentiality and access to the patient's records. See generally, 42 C.F.R. § 482.13.

³² 42 C.F.R. § 482.22. This regulation also includes requirements governing the medical staff bylaws themselves, including that they are approved by the governing body, and that they include requirements that medical history and physical examinations are completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or any procedure requiring anesthesia. The bylaws must also require that an updated examination of the patient (including changes in condition) is conducted within 24 hours of admission or registration (but also prior to surgery or a procedure requiring anesthesia). Finally, unusual deaths and cases of “medical-legal and educational interest” must result in an autopsy.

³³ “Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors,” OIG and AHLA.

the subject, and in subsequent publications.³⁴ In a publication authored jointly by members of the American Health Lawyers Association (AHLA) and the OIG, directors are instructed that, as part of their fiduciary duty of care, they are expected to “exercise general supervision and oversight of quality of care and patient safety issues.”³⁵ The document discusses how these efforts involve being attentive to specific quality of care measurement and reporting requirements.³⁶ It further explains that “all levels of a health care organization, from the direct caregiver to the governing body of an institutional provider, could face liability for failing to meet the quality of care obligations applicable to government program providers.”³⁷ The key issue here is that board members are expected to monitor quality performance of their organizations, and may face liability if they turn a blind eye to existing problems. This will necessarily include reports submitted to Federal and state authorities regarding quality of care.

The OIG and Federal prosecutors also target claims submissions on the basis of quality fraud. Typically the Federal False Claims Act (FCA) serves as the basis for the lawsuit. In general, the FCA makes it a civil offense for any person to knowingly submit or cause to be submitted a false or fraudulent claim for payment.³⁸ Violators are subject to a civil penalty of between \$5,000 and \$10,000 per incident, plus three times the damages sustained by the government.³⁹ In recent years, the FCA has been employed by Federal prosecutors against individuals who submitted claims for payment under Medicare which were based on a theory whereby the fraudulent statement is an implied statement regarding the quality of the services provided.

For example, in Zurich American Ins. Co v. O’Hara Regional Center for Rehabilitation, 529 F.3d 916 (C.A.10 2008), a Colorado long-term care facility was sued for having systematically and routinely understaffed its facility in violation of its provider agreement with the Medicare and Medicaid programs. The Court of Appeals for the Tenth Circuit explained that,

³⁴ “Driving for Quality in Acute Care: A Board of Directors Dashboard” Government-Industry Roundtable, November 10, 2008. “Driving for Quality in Long-Term Care: A Board of Directors Dashboard,” Government-Industry Roundtable, December 6, 2007.

³⁵ “Corporate Responsibility and Health care Quality: A Resource for Health Care Boards of Directors,” OIG and AHLA, p. 3.

³⁶ “Corporate Responsibility and Health care Quality: A Resource for Health Care Boards of Directors,” OIG and AHLA, p. 3-4.

³⁷ “Corporate Responsibility and Health care Quality: A Resource for Health Care Boards of Directors,” OIG and AHLA, p. 6.

³⁸ 31 USCA § 3729(a)(1)(A). Additionally, false claims liability will apply to anyone who “knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” 31 USCA § 3729(a)(1)(G).

³⁹ 31 USCA § 3729(a)(1).

“The crux of the government’s claim is that O’Hara promised to provide a certain level of patient care; it represented to the government it provided the contractually agreed levels of care; but, in fact, it did not provide the agreed services. As we read the government’s cause of action, the problem was not the actual level of services provided to O’Hara’s patients, but rather that O’Hara billed for services it did not provide – namely enhanced services. This violates the provider agreements.”⁴⁰

The key issue in this case is that the certification implied in the submission of claims for reimbursement alone acted as the false claim, because it implied that the facility had sufficient staffing levels as required by the contract, when in fact it did not. Although this case focused primarily on O’Hara’s dispute with its insurer over whether the insurer was contractually obligated to defend and indemnify O’Hara for false claims liability, the court’s discussion illustrates the underlying theory of the implied statement of quality of care.

The government’s approach in this regard, however, is nothing new. In 1996, a community psychiatric facility was sued by the Federal government under the FCA. The District Court for the Western District of Oklahoma described the government’s argument that the facility had knowingly submitted claims for in-patient psychiatric care of Medicaid patients, and by submitting such claims had implicitly certified that it was abiding by requirements regarding the quality of care and the safety and security of the patients’ environment, which the facility knew was not the case.⁴¹ The government alleged that the facility had not taken appropriate precautions to protect patients from physical injury and sexual abuse, claiming that the facility was understaffed, lacked necessary monitoring equipment, and used inappropriate housing assignments.⁴²

Moreover, on May 20, 2009, the Federal Enforcement Recovery Act (FERA) became law. This act modified the FCA, among other ways, to explicitly apply to

⁴⁰ Zurich American Ins. Co. v. O’Hara Regional Center for Rehabilitation, 529 F.3d 916 (C.A.10 2008), at 921-922.

⁴¹ U.S. ex rel. Aranda v. Community Psychiatric Centers of Oklahoma, Inc., 945 F.Supp. 1485 (W.D. Okla. 1996).

⁴² An assertion of quality failures as a basis for false claims liability, however, is not an unassailable argument. In U.S. ex rel. Mikes v. Straus, 84 F.Supp.2d 427 (S.D.N.Y. 1999), the District Court for the Southern District of New York granted a defendant’s motion for summary judgment against claims brought by a relator that the defendant had improperly performed spirometry tests, which amounted to negligence, and that the defendant had breached the medical necessity standards contained in 42 U.S.C. § 1320c-5(a). The court found that Medicare payment was not conditional upon adherence with § 1320c-5, and that the relator had not established the requisite intent. Similarly, in U.S. ex rel. Landers v. Baptist Memorial Health Care Corp., 525 F.Supp.2d 972 (W.D.Tenn. 2007), the District Court for the Western District of Tennessee granted a defendant’s motion for summary judgment based on a determination that the relator had failed to show that non-compliance with Medicare’s Conditions of Participation imposed False Claims Act liability under either an express or implied certification theory.

retention of overpayments.⁴³ The new language applies FCA liability to “anyone who knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.”⁴⁴ The term “obligation” is defined to include “retention of any overpayment.”⁴⁵ Whereas retention of an overpayment was previously not explicitly included in the statute, it is clear that the government now considers any knowing retention of overpayments to create False Claims liability. The implications of this revision are directly relevant to quality reporting. Health care providers that retain payments based on improperly reported statements of quality now may run afoul of the FCA.

The OIG has made it clear that it intends to enforce against providers and hold them accountable for the quality of their care as a component of the OIG’s overall efforts to curtail fraud and abuse. This focus is unlikely to shift in the future and may only intensify. In a recent statement before the U.S. Senate Committee on Finance, Chief Counsel for the Office of Inspector General, Lewis Morris, discussed the need to curb fraud, waste, and abuse as an essential component of the health care reform strategy.⁴⁶ In his statement, Mr. Morris discussed five principles to combat health care fraud, waste, and abuse. Among these principles were the need to: scrutinize individuals and entities wishing to participate in Federal health care programs prior to their enrollment; assist health care providers and suppliers in adopting practices to promote compliance with program requirements, including quality and safety standards; and respond swiftly to and impose punishment sufficient to deter others in detected cases of fraud.⁴⁷ The OIG’s Work Plan for Fiscal Year 2010 also specifically lists payments for E-prescribing Initiative incentives as an area that the OIG intends to review.⁴⁸ Additionally, the Centers for Medicare and Medicaid Services (CMS) have incorporated several “never events” into the payment rules of the Medicare program.⁴⁹ These “never

⁴³ 31 U.S.C.A. § 3729(a)(1)(G). For a more in-depth discussion of FERA and its implications, see Kass, Julie E. and Chelsea Rice, “The New False Claims Act: Reverse Overpayment Provisions Create Even Greater Issues Under the Stark Self-Referral Law,” Health Law Handbook, 2010 ed., pp. ___ to ___.

⁴⁴ 31 U.S.C.A. § 3729(a)(1)(G).

⁴⁵ 31 U.S.C.A. § 3729(b)(3).

⁴⁶ Formal Statement of Lewis Morris, Chief Counsel to the Inspector General, before the U.S. Senate Committee on Finance’s April 21, 2009, “Roundtable Discussion on Health Care Reform,” April 21, 2009. <http://oig.hhs.gov/testimony/docs/2009/HealthReformSenFinanceLMorris.pdf>.

⁴⁷ Formal Statement of Lewis Morris, Chief Counsel to the Inspector General, before the U.S. Senate Committee on Finance’s April 21, 2009, “Roundtable Discussion on Health Care Reform,” April 21, 2009, p. 2. <http://oig.hhs.gov/testimony/docs/2009/HealthReformSenFinanceLMorris.pdf>.

⁴⁸ Office of Inspector General: Work Plan for Fiscal Year 2010, pp. 28-29. http://oig.hhs.gov/publications/docs/workplan/2010/Work_Plan_FY_2010.pdf.

⁴⁹ Medicare National Coverage Determinations Manual, Chapter 1 §§ 140.6 – 140.8. As of 2007, ten states had also adopted the “never events.”

events” include instances such as wrong site surgeries, transfusions using the wrong blood type for the patient, and serious injuries and deaths. These reporting requirements apply to services rendered beginning January 15, 2009, and deny coverage for wrong patient, wrong surgery, and wrong site errors.⁵⁰ The “never events” concept was created by the National Quality Forum (NQF).⁵¹ As of January, 2009, the NQF has entered into a contract with CMS to begin development of other quality measures and efforts, ranging from promotion of EHR adoption, to reviewing evidence relating to twenty medical conditions which account for over 95% of Medicare’s costs in order to develop measures to improve care and reduce costs.⁵²

2.2. Mandatory State Quality Reporting Efforts

Most states employ medical error reporting systems for quality control, generally as a condition of licensure. These statutes and regulations typically apply to hospitals, nursing homes, and sometimes physicians. Outcomes of care are the most typical focus regarding adverse events. Failure to promptly and properly report usually carries financial penalties, although these may be minor. More significantly, failure to report may adversely affect a health care provider’s licensure.

States typically require some form of hospital adverse event reporting. For example, California’s Health & Safety law requires hospitals to report wrong site or wrong patient surgeries, foreign objects left in a patient after surgery, death of a patient during surgery or up to twenty-four hours after surgery, death or disability of an otherwise healthy patient from contaminated drugs or biological, infants discharged to the wrong parents or guardians, and other similar events.⁵³ The hospital must report such events within five days of discovery, or within twenty-four hours if the event is ongoing.⁵⁴ When there is an ongoing threat of imminent danger, death, or serious bodily injury, the California Department of Health will conduct an investigation within forty-eight hours of receiving notice. Moreover, until the problem is resolved, the Department may conduct spot inspections for up to a year following notification. Failure to report the adverse event will result in a civil penalty of \$100 per day, per event.⁵⁵

⁵⁰ <http://www.cms.hhs.gov/transmittals/downloads/R101NCD.pdf>.

⁵¹ http://www.qualityforum.org/Publications/2002/Serious_Reportable_Events_in_Healthcare.aspx. The NQF is a private, non-profit organization which has established certain quality-based standards, including the “never events.”

⁵² http://www.qualityforum.org/About_NQF/HHS_Performance_Measurement.aspx.

⁵³ California Health & Safety Code § 1279.1. California state regulations require additional reporting of “unusual occurrences,” such as epidemics, fires, poisonings, major accidents, disasters, etc. 22 CA ADC §§ 70733-70737.

⁵⁴ California Health & Safety Code § 1279.1. California state regulations require additional reporting of “unusual occurrences,” such as epidemics, fires, poisonings, major accidents, disasters, etc. 22 CA ADC §§ 70733-70737. *Id.*

⁵⁵ California Health & Safety Code § 1279.2.

New York law requires similar reporting for events such as patient deaths or injuries, but also requires reports of fires, equipment malfunctions, staff strikes, and other such incidents.⁵⁶ Additionally, hospitals must report acquired infections.⁵⁷ In general, violations of New York's health laws are treated as a misdemeanor punishable by up to a year in jail and a \$2000 fine.⁵⁸

In September, 2009, a New Jersey law was passed mandating that hospitals report a wide range of medical errors, including foreign bodies left during a procedure, postoperative sepsis, air embolisms, and postoperative hip fractures.⁵⁹ In addition, hospitals in New Jersey may not collect payment from a patient or third-party payer for any of the reportable events.⁶⁰ While New Jersey regulations already required reporting similar events to the State Department of Health and Senior Services,⁶¹ the new law will report such information publicly.

Texas requires hospitals and treatment facilities to report revenues (including Medicare, Medicaid, other state revenues, local government revenues, tax support, and charitable contributions). Additionally, admissions, discharges, patient days, and average length of stay must be reported.⁶² While the type of information being reported here might not seem directly connected to quality of care, average length of stay could be seen as indicative of quality of care. Hospitals which fail to submit such data and which fail to respond to notices from the Department of Health are subject to civil penalties of \$500 for each day that the data goes unreported.⁶³ Texas also prohibits hospitals, treatment facilities, and health care professionals from billing patients for treatment that the hospital or health care professional knows were improper, unreasonable, or medically or clinically unnecessary.⁶⁴

⁵⁶ New York Public Health Law § 2805-1.

⁵⁷ New York Public Health Law § 2819.

⁵⁸ New York Public Health Law § 2805-1. The liability in this case is personal liability, with the law referring to "a person who violates."

⁵⁹ N.J.S.A. 26:2H-12.25b. This section also requires reporting the following incidents: iatrogenic pneumothorax; postoperative hemorrhages and hematomas; postoperative deep-vein thrombosis or pulmonary embolisms; postoperative wound dehiscence; accidental punctures or lacerations; transfusion reactions; birth traumas; obstetric traumas in vaginal deliveries both with and without instruments; and surgery at the wrong site, on the wrong body part, on the wrong patient, or where the wrong surgery is performed on a patient.

⁶⁰ N.J.S.A. 26:2H-12.25c.

⁶¹ N.J.A.C. 8:43E-10.6.

⁶² Vernon's Texas Code Annotated, Health and Safety Code § 311.033. For example, Texas hospitals may simply report "Average length of stay is four days" without indicating reasons why.

⁶³ Vernon's Texas Code Annotated, Health and Safety Code § 104.043.

⁶⁴ Vernon's Texas Code Annotated, Health and Safety Code § 311.0025. These entities are also prohibited from billing for services they know were not rendered.

As with the hospital reporting requirements, many states also embed physician reporting requirements for adverse events into their state licensure statutes and regulations. For example, under Pennsylvania law, health care workers at a health care facility who believe a “serious event” (such as a patient death or injury) or an “incident” (such as a “near miss”) has occurred must report within twenty-four hours in accordance with the facility’s plan.⁶⁵ Similar requirements apply to health care facilities, and failure to report will result in a \$1,000 per-day fine.⁶⁶

Under California law, physicians must report malpractice settlements over \$30,000 and judgments or arbitration awards of any amount, if the licensee does not hold professional liability insurance.⁶⁷ In addition, they must report the bringing of an indictment or information charging a felony against them, as well as any conviction, including any guilty verdicts, guilty pleas (or pleas of no contest) for any felonies or misdemeanors.⁶⁸ Physicians who perform scheduled medical procedures outside of a general acute care hospital which results in the death of the patient must report the event to the Board of Medicine within fifteen days.⁶⁹

Many states also publish report cards for hospitals and/or physicians, as well as health plans.⁷⁰ For example, New Jersey publishes reports on hospitals, nursing homes, home health agencies, ambulatory surgical centers, physicians (including podiatrists and optometrists, and managed care plans.⁷¹ Maryland⁷², New York⁷³, Pennsylvania⁷⁴, and Oregon⁷⁵ all also publish reports on health care providers and/or health care plans.

⁶⁵ 40 P.S. § 1303.308.

⁶⁶ 40 P.S. § 1303.313.

⁶⁷ California Business & Professions Code § 801.01(b)(2).

⁶⁸ California Business & Professions Code § 802.1.

⁶⁹ California Business & Professions Code § 2240. This also applies when the service is performed by a person acting under the physicians’ orders or supervision.

⁷⁰ For a more thorough examination of this topic, see Shay, “Commerce in Provider Data: What, Why and Provider Contractual Controls,” Health Law Handbook, 2005 edition, pp.294-296; and, Gosfield, “Health Care Report Cards: Quality in the Public’s Cross Hairs,” Health Law Handbook, 2000 edition, pp. 501-542.

⁷¹ <http://www.state.nj.us/health/healthfacilities/reportcards.shtml>.

⁷² <http://mhcc.maryland.gov/consumerinfo/index.html>. Maryland posts reports on ambulatory surgical facilities, hospitals, nursing homes, long term care, and health insurance.

⁷³ <http://www.health.state.ny.us/nysdoh/healthinfo/index.htm>. New York posts reports on hospitals, physicians, nursing homes, and hospices and home health agencies.

⁷⁴ <http://www.phc4.org/hpr/>.

⁷⁵ http://www.oregon.gov/OHPPR/HQ/Hospital_Specific_Reports.shtml.

With respect to state-level enforcement efforts, the story is checkered. Maryland has fined hospitals for failing to report patient deaths or injuries. In May, 2009, state health officials fined Doctors Community Hospital \$30,000 for failure to report one patient death and at least seven serious injuries resulting from errors by the medical staff.⁷⁶ Similarly, in Illinois, a pregnant woman suffering from schizophrenia died in an emergency room at Riveredge Hospital on August 10, 2007. Her death went unreported for a year until an employee complained to state regulators. Although the state issued no citation, a February 26, 2009 report in the Chicago Tribune noted that the state regulators had conceded that they had erred in failing to issue a citation for the hospital's failure to report the death.⁷⁷ In Pennsylvania, patients at Fox Chase Cancer Center, Mercy Fitzgerald Hospital, and Abington Memorial Hospital were all injured due to poor quality care (such as objects left inside the patient's body after surgery, extensive post-operative bleeding, and bedsores), but none of the hospitals reported the problems to the Pennsylvania Department of Health. In 2008, five years after Pennsylvania passed laws requiring hospitals to report such incidents, only four hospitals in southeastern Pennsylvania had been cited by the Department of Health, and none had been fined.⁷⁸ Although the Pennsylvania example shows a lack of enforcement, after such public reports, it is possible that the Department of Health will both scrutinize hospitals more closely and take steps beyond mere citations against hospitals that fail to report. In 2001, the Florida Office of Program Policy Analysis and Government Accountability conducted an audit which found that many Florida hospitals failed to report physician errors.⁷⁹ In New York, Kings County Hospital failed to report any errors between 2006 and 2008. However, at least one patient was the victim of an improper diagnosis during that time.⁸⁰ In North Carolina administrators in a state mental hospital failed to report four patient deaths to investigators, as required by state law. Two patients died while restrained. The director of the hospital informed officials that he was unaware his facility has violated state law until reading a local newspaper article questioning why an August 31, 2007 death was not disclosed. The failure to disclose occurred after the facility had been cut off (on August 25, 2007) from Medicare and Medicaid payments.⁸¹ Had

⁷⁶ Insurance Journal, "Maryland Hospital Fined after Failure to Report Errors," June 16, 2009.
<http://www.insurancejournal.com/news/east/2009/06/16/101440.htm>.

⁷⁷ "Riveredge Hospital patient's death went unreported to Illinois," February 26, 2009.
http://archives.chicagotribune.com/2009/feb/26/local/chi-riveredge_sidefeb26.

⁷⁸ "Hospitals' mistakes are going unreported," September 12, 2008.
http://www.philly.com/inquirer/home_top_stories/20080912_Hospitals_mistakes_are_going_unreported.html.

⁷⁹ "Audit: Some hospitals failed to report medical mistakes," St. Petersburg Times, May 17, 2001.

⁸⁰ The victim, Gradford Dennie, presented at the hospital after suffering a massive stroke which paralyzed his left side. At the hospital, nurses noted that his right leg was black and blue and cold to the touch (common symptoms of gangrene – although no reference to gangrene was ever made in the record. Dennie ultimately had to have his leg amputated above the knee.

⁸¹ "Hospital did not report 4 deaths," The News & Observer, December 8, 2007.
www.newsobserver.com/news/v-print/story/818350.html.

effective quality reporting compliance protocols been in place, these hospitals would not have failed to report the incidents.

2.3 Optional Federal Reporting Programs

Not all quality reporting is mandated by law; some reporting is optional or draws its information from “opt-in” sources. At the Federal level, the two largest current physician initiatives are the Medicare Physician Quality Reporting Initiative (PQRI) and the E-Prescribing Initiative. Under PQRI, physicians are paid an additional 2.0 percent on their total Medicare revenue for reporting certain data.⁸² For reporting in 2010, the PQRI program tracks 179 independent measures of quality.⁸³ Some of the measures include, for example: the percentage of patients aged 18 years and older diagnosed with chronic Hepatitis C who are prescribed specific antiviral drugs; the percentage of patients who receive preventative care such as influenza vaccines, and screenings for breast and colorectal cancer; the percentage of patients who are smokers advised by their doctors to quit smoking; and, whether the reporting provider has adopted and is using a qualified electronic health record.⁸⁴

These measures are reported using the CMS-1500 claims form. The measures themselves indicate a minimum standard of quality adopted by Medicare. For example, measure #108 for the 2010 PQRI program tracks the percentage of patients aged 18 or older who have been diagnosed with rheumatoid arthritis and prescribed disease-modifying anti-rheumatic drug therapy.⁸⁵ Although many of the measures simply require physicians to report the required information on the claims form, the implication of the measures relate to the “quality” of the health care, although there is no conclusion drawn as to whether the care reported was good or bad. Improperly reporting the measures may subject the physician to overpayments or potential False Claims Act liability. Similarly, the E-Prescribing Incentive Program was initiated with the passage of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA). In the 2009 Medicare Physician Fee Schedule Final Rule, CMS described several of the advantages of adopting an electronic prescribing system, including: improving patient safety and quality of care by reducing illegibility, reducing oral miscommunications, providing warnings and alert systems, and providing access to patient medication histories; automation of renewals and authorization; and, improving formulary adherence.⁸⁶ Under the E-Prescribing Incentive Program, a “successful electronic prescriber” will qualify for

⁸² <http://www.cms.hhs.gov/PQRI>.

⁸³ For a full list of the measures, see, http://www.cms.hhs.gov/PQRI/Downloads/2010_PQRI_MeasuresList_111309.pdf.

⁸⁴ http://www.cms.hhs.gov/PQRI/Downloads/2010_PQRI_MeasuresList_111309.pdf. Although adoption of an e-prescribing measure was included in the 2008 PQRI program, this measure was dropped beginning in 2009. The separate Medicare E-Prescribing Initiative now tracks the use of qualified e-prescribing systems.

⁸⁵ http://www.cms.hhs.gov/PQRI/Downloads/2010_PQRI_MeasuresList_111309.pdf.

⁸⁶ 73 FR 69847, November 19, 2008.

an increase of up to 2.0 percent for covered professional services by meeting the program's reporting requirements.⁸⁷ To receive the payment increase (and later avoid the payment decrease), "successful electronic prescribers" must report one of three codes on at least 50 percent of applicable cases.⁸⁸ The three codes indicate that (1) all prescriptions were generated on a qualified system, (2) no prescriptions were generated, or (3) a qualified system was adopted, but no pharmacy could receive the transmissions.⁸⁹ However, the provider must use a "qualified system," which can: generate a complete active medication list which incorporates electronic data received from applicable pharmacies (if available); allow eligible professionals to select medications, print and electronically transmit prescriptions, and conduct written or audio alerts to warn of inappropriate doses or drug interactions; provide information relating to lower cost, therapeutically appropriate alternatives; provide information on formulary or tiered formulary medications, patient eligibility, and authorization requirements received electronically from the patient's drug plan.⁹⁰ If the provider submits claims using the E-Prescribing Initiative measures, it is making an implicit statement that its e-prescribing system is a "qualified system." If for some reason the system is not qualified, the provider may be exposed to False Claims Act liability, or at the very least may be required to pay back any amounts that were based on erroneous submitted claims. Considering that the incentive payment applies to all covered Part-B services rendered during the reporting period (not simply the services for which the measures were reported), potential overpayments or False Claims Act exposure could be substantial.

CMS has also initiated reporting programs for hospitals relating to inpatient and outpatient services. The Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) and the Hospital Outpatient Quality Data Reporting Program (HOPQDRP) require hospitals to submit data on measures relating to patient care. For 2010, hospitals

⁸⁷ The 2.0 percent increase is only available for providers deemed "successful providers" in 2009. A 1.0 percent increase will be offered to successful providers in 2010 and 2011, and a 0.5 increase will be offered in 2012. Additionally, a 1.0 percent decrease in all covered professional services will be imposed beginning in 2012 on any eligible professional who is not a "successful electronic prescriber" for the reporting year, increasing to 1.5 percent in 2013, and 2.0 percent for 2014 and subsequent years. 73 FR 69847-69848. These changes to the provider's payment rates are separate from other changes applicable under PQRI or the Hospital Outpatient Department Quality Measures Program.

⁸⁸ 73 FR 69848, November 19, 2008.

⁸⁹ See, <http://www.cms.hhs.gov/ERxIncentive/>.

⁹⁰ 73 FR 69849-69850. Additional requirements include that medication lists are generated and prescriptions are transmitted electronically using the National Council for Prescription Drug Programs Prescriber/Pharmacist Interface SCRIPT Standard, Implementation Guide, Version 8, Release 1, October 2005; that information be provided on lower cost alternatives using the NCPDP Formulary and Benefits Standard, Implementation Guide, Version 1, Release 0 (Version 1.0), October 2005 (NCPDP Formulary and Benefits 1.0); and that information on formulary or tiered formulary medications, patient eligibility, and authorization requirements uses the NCPDP Formulary and Benefits 1.0, or one of two other standards. Additional specifics on functionality may be imposed in the future.

must report on 11 outpatient measures across 3 different areas⁹¹ and 46 inpatient measures across 9 areas.⁹² If a hospital fails to report, CMS will reduce its annual payment update factor by 2.0 percent for the reporting year.⁹³ In January, 2009, CMS announced that 3,313 out of the total 3,339 hospitals participating in the programs (or 99.3%) had fulfilled the reporting requirements for 2008.⁹⁴ For fiscal year 2009, CMS reports that 96% of hospitals reported properly for inpatient measures.⁹⁵ Admittedly, these programs are heavy-handed examples of “opt-in” programs. However, hospitals may still participate in Medicare even if they fail to report, in contrast to their continuing requirements to maintain their enrollment status and meet the Medicare Conditions of Participation.

Some states are also beginning to track quality measures, typically through pay for performance programs in state Medicaid programs. For example, Minnesota is currently developing a “pay-for-performance” system. The system is still in its infancy, however, with final recommendations from the state Department of Health having only been published in March, 2009.⁹⁶ Pennsylvania’s Medicaid program also operates a pay-for-performance system for physicians.⁹⁷ The program measures both outcomes-focused and process-focused data. For example, beginning January 1, 2010, providers may receive \$45 per coronary artery disease patient who achieves an LDL level of less than or equal to 100, and \$10 per congestive heart failure patient who adheres to beta blocker therapy up to four times per year.⁹⁸ In New York, beginning January 1, 2010, eligible

⁹¹ See, Specifications Manual for Hospital Outpatient Department Quality Measures v3.0, available at www.qualitynet.org. The measures are organized into three sections relating to: (1) acute myocardial infarctions (AMI); (2) outpatient surgery; and, (3) imaging efficiency. Measures for AMI include aspirin on arrival at the emergency department, median time to transfer to another facility for acute coronary intervention, and median time to fibrinolysis. Outpatient surgery measures include: timing of antibiotic prophylaxis, and prophylactic antibiotic selection for surgical patients. Imaging efficiency measures include: MRIs of lumbar spine for low back pain, and use of contrast material in thorax CT scans.

⁹² See, http://www.cms.hhs.gov/HospitalQualityInits/08_HospitalRHQDAPU.asp for the list of inpatient measures hospitals must report to qualify for the FY 2011 update.

⁹³ Social Security Act § 1886(d)(3)(B)(vii)(I); 42 CFR § 412.64(d).

⁹⁴ “CMS Announces First Results of Hospital Quality Reporting Initiative for Outpatient Services,” January 8, 2009, <http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=3397&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=false&choOrder=date>. At the time of this writing, there has been no report issued on hospital reporting for outpatient measures in FY 2009.

⁹⁵ http://www.cms.hhs.gov/HospitalQualityInits/08_HospitalRHQDAPU.asp.

⁹⁶ See, <http://health.minnesota.gov/healthreform/measurement/qips.html>, and <http://health.minnesota.gov/healthreform/measurement/FinalRecs.pdf>.

⁹⁷ <http://www.accessplus.org/PayForPerformance.aspx>.

⁹⁸ http://www.accessplus.org/downloads/P4P/P4P_SummaryPaymentOpportunities.pdf.

Medicaid prescribers may receive \$0.80 per dispensed Medicaid e-prescription, provided that the software used to transmit the subscription is certified by the Certifying Commission for Health Information Technology.⁹⁹ As with some of the Federal “opt-in” programs, these programs represent an opportunity for health care providers to gain additional revenue – but require vigilance to ensure that reports and/or claims are accurately submitted.

.3 Avoiding Quality Speed Traps

Given the potential risks in misreporting quality metrics, including potential Federal False Claims liability; the range of reporting systems that healthcare providers face, both mandatory and optional, and the likelihood that quality measurement will become an increasingly important part of controlling health care costs, it is critical that health care providers and their compliance officers develop appropriate methods to ensure compliance with reporting requirements. Towards this end, providers should strongly consider developing a formal compliance program focused specifically on quality reporting. If the provider already has a compliance program in place, this task will be easier.

In general, the OIG recommends a seven step process for developing a compliance plan: (1) conduct internal monitoring and periodic audits; (2) implement compliance and practice standards by developing written standards and procedures; (3) conduct appropriate training and education on standards and procedures; (4) designate a chief compliance officer (and other appropriate bodies as necessary and appropriate for the provider) to monitor compliance efforts and enforce standards; (5) develop and maintain systems of communication to facilitate adherence to compliance; (6) develop a system to respond appropriately to detected violations and to disclose to appropriate government entities; and, (7) enforce disciplinary standards.¹⁰⁰

Much of the guidance applicable to general compliance programs can be adapted for quality reporting compliance; the overall steps towards developing a quality reporting compliance program should be no different than the steps described above. In general, quality reporting compliance – as with general compliance – will come down to two basic principles: (1) do it right, and (2) if a mistake is made, fix it. This chapter presumes that the reader is familiar with general compliance concepts, as well as the various Model Compliance Guidance publications issued by the OIG.¹⁰¹ Accordingly, the remainder of

⁹⁹ <http://www.nyacp.org/files/NOV09%20Medicaid.pdf>. The e-prescription must also conform with Medicare Part-D standards, and must be encrypted.

¹⁰⁰ 63 FR 8989; 65 FR 59436.

¹⁰¹ In particular: the OIG Compliance Program for Individual and Small Group Physician Practices, 65 FR 59434; the OIG Compliance Program Guidance for Hospitals, 63 FR 8987; and, the OIG Supplemental Compliance Program Guidance for Hospitals, 70 FR 4858. In each of the publications, the OIG has recommended establishing one or more compliance officers. If a compliance officer already exists, a new officer or subordinate could be designated to monitor quality reporting. 70 FR 4874; 65 FR 59441; 63 FR

this chapter focuses on specific problem areas in quality reporting, and explores how different health care providers should consider addressing them in a compliance program.

3.1 National Practitioner Data Bank and Adverse Event Reporting

While no hospital has lost its peer review immunity as of 2008, the failure to properly report to the NPDB does carry such a risk. As Federal quality initiatives are developed and more data on quality is sought, enforcement of the NPDB may become more of a concern for hospitals. Hospitals therefore need to remain vigilant in meeting their reporting requirements. Towards this end, hospital compliance departments need to scrutinize the types of “adverse actions” that give rise to reporting requirements.¹⁰² To assist the compliance department’s efforts, procedures should be established that require the relevant hospital committees and departments to report to the compliance department any such “adverse actions” when they occur.

Hospital compliance departments should also use auditing and other monitoring methods to determine whether relevant committees are meeting their reporting obligations to the compliance department. Where failures are discovered, even if HHS has failed to investigate, the compliance department should take voluntary measures to report as required and indicate how the hospital has taken steps to correct the matter so that future problems will not occur.

Similar to NPDB reporting requirements, state law may require health care providers to report “adverse events” (likely including, but not limited to the more specific “never events”). A quality reporting compliance plan should address how “adverse events” are treated, and what procedures they trigger. The occurrence of an “adverse event” will raise several issues for a health care provider. Of course, the provider will need to focus on the civil liability arising from the event. However, the provider should be certain that it reports the event as required to the appropriate state authority, once it is discovered.

Both in the hospital setting and in the physician practice setting, the quality reporting compliance program should specify the procedures by which the event is reported to the individuals responsible for compliance, as well as to any additional committees or groups (such as a peer review committee), and to the Board of Directors. However, an adverse event should also trigger procedures to ensure that claims are not submitted to Federal or state payors for the medical services related to the adverse event. Medicare already refuses to cover services rendered as part of a “never event,” and the OIG has made it clear that where the quality of medical services is so low as to constitute no care at all, the OIG will consider imposing Federal False Claims liability on a provider

8993. The OIG describes the role of the compliance officer as both a watchdog for the provider, with the authority to initiate audits and conduct oversight activities, and as a point of contact for the provider’s board and/or individual practitioners.

¹⁰² Such scrutiny may intensify due in no small part to reports such as at note 22, *supra*, which indicate that hospitals either fail to report or avoid reporting requirements by disciplining physicians in ways which do not trigger them.

submitting claims for such services. “Never events” and other similar “adverse events” will almost certainly fall into this category.

While many state licensure boards and departments of health consider gross error to be grounds for suspension or termination of a physician’s license, without a reporting scheme in place, they are unlikely to have a means by which to compel compliance. This may change, however, as professional licensure boards and other state agencies focus more on quality of care. Likewise, most hospitals are required to report “adverse events” to the state department of health within a given timeframe. Accordingly, any quality reporting compliance plan should address the reporting requirements for “adverse events,” including deadlines and information required to be submitted.

For example, consider the following scenario. A patient presents at a California hospital for surgery and is operated on by a physician member of the medical staff. The surgeon in question malpractices the patient, operating on the wrong site. The patient sues, and the surgeon settles the case. In this situation, the hospital must report the event to the state department of health within five days of discovering the error. If the physician loses clinical privileges for thirty days or more, the hospital must also report to the NPDB. The physician must also report the malpractice settlement to the state medical board if the settlement is for more than \$30,000. Obviously, no claim should be submitted for the services. Both the hospital and the physician’s practice should structure their respective quality reporting compliance programs to address how the information is reported internally to compliance officers, and what procedures must be followed after discovery of the event.

3.2 Medicare Enrollment & Participation Rules

As one of the Federal government’s primary means of restricting expenditure of Medicare dollars, the rules governing how providers gain access to the program represent a potential minefield for quality reporting compliance. Federal enforcers already treat Medicare’s conditions of participation as the potential basis for Federal False Claims liability when hospitals submit claims while not in compliance with the conditions of participation. It is no stretch, therefore, to expect that similar quality-related certifications in the physician enrollment process may be used as the basis for False Claims actions in the future. Even aside from the potential for False Claims liability, failure to comply with enrollment requirements and/or the conditions of participation can be grounds for revocation of Medicare billing privileges or expulsion from the program. With this in mind, providers need to adopt approaches towards ensuring that they both continue to comply with the requirements for participation (including those relating specifically to quality), and that they continue to report to CMS any necessary information as it changes.

The compliance program should take into account the specific information reported on the CMS-855 enrollment forms, including the interrelated aspects of the enrollment forms, and especially the deadlines for reporting changes to information, to avoid accidentally submitting claims for services when the provider was not in compliance with the enrollment requirements.

For example, imagine a scenario in which a physician who five years prior had his license in another state suspended for three months, but who was ultimately vindicated, begins to work for a provider as a managing employee. If the provider continues to submit claims to Medicare without first updating its CMS-855A or 855B enrollment form to indicate the new ownership/management interest and disclose the physician's adverse legal history, such claims could create False Claims Act liability. In this scenario, the provider is making an implicit statement (A) that its enrollment is up-to-date, and (B) that no manager of the provider has an adverse legal history that must be disclosed. That the provider knew of (A) the addition of the new owner, and (B) the owner's adverse legal history, failed to disclose it, and submitted claims anyway may create the intent necessary to attach liability under the False Claims Act. If the physician also renders billable services for the provider, the physician's CMS-855I must also be updated so that the provider may bill for the physician's reassigned claims. Accordingly, a quality reporting compliance program should include procedures for regular review of CMS-855 forms and supporting documentation, to ensure that the information is up to date.

Similarly, the hospital quality reporting program should take into account the specific requirements of the Medicare conditions of participation, to ensure that the hospital continually remains in compliance with them. For example, hospital compliance review of medical records to ensure that physicians are meeting their requirements to perform and document medical history and physical examinations prior to surgery or procedures requiring anesthesia, and no more than 30 days before or 24 hours after admission or registration, and that unusual deaths are resulting in autopsies. While utilization review departments have typically addressed these issues, in today's world they are a compliance concern.

3.3 PQRI, Hospital Quality Reporting, and the E-Prescribing Initiative

These three general areas create additional concerns for providers. Physicians participating in PQRI, hospitals reporting under the RHQDAPU and HOPQDRP to avoid losing 2.0% of their annual payment update, and providers participating in the E-Prescribing Initiative all need to develop compliance mechanisms that will ensure accurate reporting. It is also critical that providers understand that even though PQRI and hospital quality reporting for annual payment updates generally only require reporting of data rather than specific quality outcomes, falsely or inaccurately reported data can give rise to Federal False Claims liability.¹⁰³ With respect to the E-Prescribing Initiative, False Claims liability can attach when a provider's e-prescribing software does not meet the requirements for the E-Prescribing Initiative, but the provider reports that it had a qualifying e-prescribing system. Because the submission of the e-prescribing reporting codes indicates that a qualified e-prescribing system was used, all reporting codes indicating the use of an e-prescribing system presume that the system itself was qualified. Therefore, a failure to maintain a qualifying e-prescribing system can taint all codes reported, thereby forming the basis of False Claims liability if payment is made.

¹⁰³ "Corporate Responsibility and Health care Quality: A Resource for Health Care Boards of Directors," OIG and AHLA, p. 7.

As with general billing compliance efforts, quality reporting programs which require specific codes will necessitate that practitioners be trained to ensure that their medical records support the information reported on the claims form, and that billing staff receive training on proper coding. Coding for any such reporting should match what appears in practitioner medical records. The compliance program should also conduct periodic probe audits of quality measure codes to ensure accuracy. Quality reporting compliance staff must therefore be familiar both with the specific measures reported as part of such programs, and the requirements to qualify for payment increases based on reporting. At least with the E-Prescribing Initiative, this requires additional familiarity with the technical aspects of what constitutes a “qualified e-prescribing system.”

For example, consider a scenario in which a physician practice reports PQRI codes as well as E-Prescribing Initiative codes. The practice assumes that its e-prescribing system is qualified, but discovers midway through the year that it does not comply with the E-Prescribing Initiative definition of a “qualified system.” At the same time, the practice discovers that it has reported administration of influenza vaccines to 80% of its ESRD patients who received dialysis, when only 60% of the patients actually received the vaccine.¹⁰⁴ The practice faces potential False Claims liability both for the reporting of false PQRI codes, and for the reporting of false E-Prescribing Initiative codes.

3.4 Responding to Quality Reporting Problems

As with general compliance, when problems are discovered in quality reporting, providers should first determine the full scope of the problem, take appropriate corrective internal action, and report to the appropriate authorities. At the same time, corporate officers must remain informed of these matters, lest they be subjected to individual liability as well. However, some aspects of quality reporting systems require special considerations in addressing problems when they are discovered.

For many general billing compliance issues, problems are discrete. Even though, for example, a clinician’s failure to properly document a specific type of service to support medical necessity may be common across his submitted claims, payment for such claims is limited to the individual claims submissions themselves; not every claim for every service submitted by the clinician is invalidated by virtue of the specific problem. By contrast, quality reporting errors can create systemic, widespread problems. For example, failure to satisfy the Medicare conditions of participation, or failure to properly maintain Medicare enrollment may result in loss of Medicare billing privileges. When this occurs, all claims submitted after the point at which the provider failed to qualify may be considered improper, and may result in False Claims liability.

The peculiarities of quality reporting systems such as PQRI, the E-Prescribing Initiative, and the Medicare hospital quality reporting systems – specifically, how they

¹⁰⁴ PQRI 2010 measure #79 tracks claims-based reporting of the percentage of ESRD patients receiving dialysis to whom influenza vaccine is administered.
http://www.cms.hhs.gov/PQRI/Downloads/2010_PQRI_MeasuresList_111309.pdf.

compensate providers – raises additional issues in terms of addressing errors when they are discovered. Because these systems only pay at the end of the reporting year based on the entire set of reported codes, rather than on an ongoing basis based on individual claims, the potential exists for the entire additional payment to be corrupted by improperly reported codes. While it is unlikely that a single misreported code will be deemed problematic by Federal authorities, a sufficiently large group of improper codes may taint the entire universe of reported measures. Some of this may be mitigated by the specific requirements of the reporting program. For example, for 2009, the E-Prescribing Initiative only requires that 50% of claims submitted for drug services include E-Prescribing Initiative measures to qualify for payment.¹⁰⁵ It is therefore possible that a provider which improperly reports half of its codes and properly reports the remaining half to be considered as having met the minimum requirement for the payment. However, with no history of enforcement efforts or pronouncements by CMS or the OIG on how such matters will be handled, the risk remains.

Certainly, these risks make ongoing compliance – stopping problems before they happen – a priority. However, when problems are discovered, once the full scope of the problem has been determined, the provider should report the problem. In the case of a failure to satisfy Medicare enrollment requirements, or failure to properly report PQRI, E-Prescribing, or hospital inpatient or outpatient measures, the provider should inform their local Medicare contractor and be prepared to pay back all overpayments promptly.¹⁰⁶ The goal in taking such voluntary efforts is to avoid or mitigate False Claims liability and act in good faith. However, the best defense the provider can have is a pro-active quality reporting compliance program to prevent problems from occurring in the first place.

.4 Conclusion

Improved health care quality is becoming increasingly important and recognized as a means by which health care costs may be controlled. Accordingly, health care providers can expect to be subjected to new and complicated mandatory quality-measurement schemes, as well as incentivized optional quality-reporting initiatives in the coming years, both at the Federal and state levels. The current crop of quality-reporting programs may only be the tip of the iceberg. Future systems may be more draconian, similar to the Medicare Hospital Outpatient Quality Data Reporting Program, or may be incentivized similar to New York's electronic prescribing initiative. Pay-for-performance models continue to gain popularity in state Medicaid programs, and the Federal

¹⁰⁵ http://www.cms.hhs.gov/ERxIncentive/01_Overview.asp. For 2010, this has changed. Individual prescribers must report measures for 25 unique electronic prescribing events. Group practices may also now qualify for a 2.0% increase in payment if the group reports on 2,500 electronic prescribing events. An "electronic prescribing event" is defined as all prescriptions electronically prescribed during a patient visit. http://www.cms.hhs.gov/ERxIncentive/Downloads/2010GPROeRx%20Specifications_Document_111009.pdf.

¹⁰⁶ Many Medicare contractors describe procedures for voluntary repayment of overpayments. If no clear procedure is described, the provider's legal counsel can contact the Medicare contractor initially, without identifying the provider, to inquire as to how the provider should pay back the monies.

government continues to develop reporting measurements for PQRI. For health care providers, these programs may represent attractive new sources of revenue, or additional headaches – and potentially both at once. With each new set of quality reporting requirements lies the potential for improper reports – in the form of errors in explicit and implicit statements alike. As the bar raises for Medicare enrollment requirements (and as purse-strings tighten on the program as a whole), government enforcers are likely to be ever-more watchful for fraud, and creative in their enforcement schemes.

In such a landscape, health care providers need to remain vigilant in their compliance efforts, now with a particular focus on quality. Providers must expand their compliance programs to address the requirements of the new quality reporting schemes. Given the complexity and interrelatedness of various reporting requirements and the increasingly harsh results from non compliance, touching on quality of care, all providers – hospitals and physician practices – will need to consult with legal counsel as they develop their compliance programs.