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High-level stress:
Remembering the first OIG Medicare Compliance Review

an interview with Tessa Lucey

Corporate Compliance Officer/Chief Privacy Officer

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by Alice G. Gosfield, Esq.

Quality fraud: Two pathways to trouble

» Exclusions, civil money penalties, and false claims charges have been imposed for provider quality failures in the past.
» The OIG and Department of Justice now have a more refined and developing focus on quality process failures by hospitals and physicians.
» Provider quality reporting is a separate basis for false claims liability.
» It is only a matter of time until whistleblowers hone in on these two new targets.
» Providers can take proactive steps to avoid trouble.

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The fact that quality is increasingly being touted as a basis for liability under the fraud and abuse laws is fairly well recognized in the compliance community. What is less well recognized are the developing bases, activities, and theories of liability, which are being deployed both by the Department of Justice and by the Office of the Inspector General (OIG). Whistleblowers will not be far behind. This article looks first at traditional bases for enforcement for quality and then at the developing context for failures associated with (1) clinical processes themselves, and (2) quality reporting.


Gosfield

Traditional quality fraud

In terms of quality failures, it has long been the case that providers can be excluded from Medicare for providing items or services (whether or not they are eligible for benefits under Medicare and Medicaid) which are substantially in excess of the patient's needs.[1] This was the basis for the threatened exclusion of the Redding Medical Center[2] and for the facilities that have been involved in recent high-profile cases involving overuse of stents. In addition, providers may be excluded for providing services which fail to meet professionally recognized standards of care.

In addition to exclusion, a range of civil money penalties can be imposed for quality deficiencies. These include claims for a pattern of medical items or services that a person knows or should know are not medically necessary.[3] A person who provides false or misleading information that could be expected to lead to premature discharge also faces civil money penalties.[4] Where hospitals make payments to physicians to reduce services, even off a baseline of overuse, both the payment and the acceptance of the payment are subject to civil money penalties.[5] And physician incentive plans that put physicians at substantial financial risk—which entails a swing of 25% from the lowest to the highest amount the physicians could be paid—can also be subject to civil money penalties.[6]

Quality has been the basis for large false claims settlements involving criminal pleas, including United Memorial Hospital in Michigan, where the hospital paid more than $1 million in settlement of claims for medically unnecessary anesthesia pain management services.[7] During Jim Sheehan's tenure as an Assistant U.S. Attorney in

Philadelphia (1980-2007), he identified implicit quality issues as subject to false claims, such as whether services were medically necessary or met all quality requirements, including that the personnel were appropriately supervised, the supervising personnel were appropriately trained, and the personnel had appropriate clinical privileges.

More recent focus by enforcers

The OIG's Work Plans began mentioning quality and patient safety in 2003, although every single model compliance guidance mentions quality. In 2007, the OIG and the American Health Lawyers Association (AHLA) jointly published a document regarding "Corporate Responsibility in Health Care Quality" which was hospital focused, but the principles in it can be applied in many other health care settings.[8] There, the OIG distinguished between general fiduciary responsibilities and a duty to act, as in the board's responsibility for medical staff credentialing. Taking the position that oversight of the health care business enterprise entails quality as part of the core mission and that quality is linked to cost and payment, the document offers ten questions boards should ask, focused around a range of concerns that are increasingly of interest to the OIG. These include goals, benchmarks, and metrics for quality; policy standards and integration of quality assurance in corporate operations; reports to the board on performance and quality concerns; integration of quality improvement with compliance; resource allocation and support for quality improvement; and response to adverse events.

As compliance professionals know, the presence of a topic in the OIG's Work Plan does not mean that enforcement will be immediate. Rather, this is more in the nature of telling the class what to study for on the exam. Usually, issues are included in the Work Plan when Medicare Administrative Contractors or other audit agencies have identified problems or the OIG in its auditing activities has found anomalies. Often, issues in the Work Plan carry forward from year to year. These issues are especially meaningful and should be taken seriously as matters for preventive action.

In the 2009 Work Plan, OIG announced that it would conduct a study of "never events" in hospitals (including the types of events and payments by any party for them) and hospital compliance with CMS requirements associated with present on admission (POA) coding. This theme continued in 2010 with a focus on POA coding, and a review of adverse events (defined to be broader than "never events"). Here, the OIG considered national incidence among beneficiaries, methods to identify events, and review of CMS methods to implement policies on hospital-acquired conditions (HACs) in the field. They also reviewed responses of state survey and certification agencies, state licensure boards, and Medicare accreditors to adverse events, while reviewing policies and practices of CMS and selected patient safety organizations for disclosing information about adverse events.

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The Work Plan in 2011 included continuing study of adverse events, review to determine which types of facilities are more frequently transferring patients with certain POA diagnoses, and a continuing review of hospital-acquired conditions (HACs). The 2012 Work Plan included continuing review of the types of facilities transferring patients with POA conditions, but moved also to a study of whether specific hospitals transfer patients with POA conditions to other hospitals. The most recent 2013 Work Plan explicitly calls out ambulatory surgery centers and hospital outpatient departments for a review of the safety and quality of care, including in preparation for and during procedures, as well as identification of adverse events.

At the same time, states have increased requirements to report adverse events as well as implementing state report cards and commercial pay-for-performance programs.

OIG has also recently created a quality-of-care Corporate Integrity Agreement webpage[9] which parallels the regular Corporate Integrity Agreement (CIA) webpage.[10] These quality-of-care CIAs have all of the features of the basic CIA plus retention of peer review consultants. To date, two hospitals and five nursing homes are operating under quality-of-care CIAs. In the nursing home context, the general problems are underservice or failure to staff adequately. By contrast, in the hospital setting, the issues are excess procedures as in the over-stenting cases.

Quality reporting as false claims

Even before the Patient Protection and Affordable Care Act (health care reform), physicians, hospitals, and others found themselves in an environment of increased reporting regarding their quality performance. For physicians, this is predominantly in the Physician Quality Reporting System (PQRS), and for hospitals this includes reporting of adverse events as well as inpatient and outpatient core measures. At the same time, states have increased requirements to report adverse events as well as implementing state report cards and commercial pay-for-performance programs. Even during the era of Jim Sheehan's role as an Assistant United States Attorney, the Department of Justice was focused on false data reported, false statements in support of a claim, false statements to avoid repayment to the government, and any false statement made in the mail or via a wire.

Interest in reported quality was identified in the OIG/AHLA paper, specifically citing quality reporting and measurement, and noting concerns about inconsistency in data and identification of quality problems not acted upon. Those issues are, of course, subject to the "intent" standards that include claims submitted by a provider who should have known of their falsity or acted in "reckless disregard" or "deliberate ignorance" of the truth or falsity of the claims.

The 2009 Work Plan identified the reliability of hospital-reported quality measurement data. The 2010 Work Plan continued to review that reliability; and in 2011 and 2012, expanded to a study of the extent to which hospital systems captured adverse events in 2010 and reported them to external agencies. Study of the reliability of hospital-reported quality measure data also continued.

Whistleblower risks

As whistleblower claims have continued to thrive and expand, these new avenues of potential false claims open the door to additional whistleblower cases. Medicare hospital claims data is publically available. The pneumonia upcoding cases of a number of years ago came from a Freedom of Information Act request where a consultant analyzed the claims data. A Washington DC district court has ordered Medicare physicians' claims data to be released.[11]

Given the government's emphasis on implicit falsity in claims, the types of issues that insider whistleblowers might allege could include:

- an insufficient number of nurses assigned to a unit to render appropriate care;
- unavailability of resources required by clinical practice guidelines;
- inadequate equipment;
- untrained, unqualified personnel performing skilled services;
- inadequate supervision; or
- failure to provide the six planks of the Institute for Health Care Improvement's "100,000 Lives Campaign" of several years ago.[12]

For physicians, it is only a matter of time until whistleblowers target the same under-service issues by them. By the same token, given the "Choosing Wisely" campaign[13] regarding unnecessary medical services, whistleblower claims on the overuse side of the continuum can also be expected.

Action steps

These developments make it clear that compliance professionals need to integrate quality-relevant liabilities into their work. The first step is to become familiar with the quality metrics, report card, and transparency initiatives relative to your enterprise. Making sure you know what data populates them will be critical. Find out who in your business is reporting what and to whom about quality. It will be increasingly important to monitor reportable data for accuracy, consistency among reports, timeliness, completeness, and clues to other problems. It would be wise to develop a plan in this regard. Carefully review any marketing or advertising for quality claims. Jim Sheehan has traditionally referred to these as "promises made but not kept." Include quality-relevant and enforcement challenges in your compliance program. Team up with Risk Management and Quality Assurance to collaborate on these issues.

Finally, in today's world, where alignment between physicians and hospitals is an increasingly major strategic emphasis, true clinical integration that incorporates explicit standardization of care to deliver high quality and value can help prevent liability and will be important to succeed in an ever-more-dangerous landscape.[14]

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3. 42 USC §1320a-7a(a)(1)(e)
4. 42 USC §1320a-7a(a)(3)
5. 42 USC §1320a-7a(b)
6. 42 CFR 422.208
7. Shellie Karno: The Criminal Prosecution of a Medical Malpractice Case. March 11, 2005. Available at http://www.lowis-gellen.blogspot.com/2005/03/criminal-prosecution-of-medical.html
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