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Quality of Care Issues: How are they perceived by the Enforcers?

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Quality of Care Issues

In recent years, there has been a serious focus on quality of care cases by the federal government. In countless matters, the federal government has intervened in cases where patient safety was in jeopardy or serious harm or death occurred to beneficiaries.

The United State Government (USG) has treated such matters as false claims. In many cases, unlicensed doctors have treated patients and billed Medicaid, pediatricians have charged Medicaid for inoculations of needy children, where the serum was provided free of charge, skilled nursing facilities (SNF) have been cited for poor wound care, gone through the motions for regulators and still rendered sub-standard care to patients, in some cases leading to death or serious health consequences.

In Connecticut, a SNF patient was sent to an emergency room. Upon arrival the patient was in such poor condition that hospital staff notified state authorities. The patient was diagnosed with a septic infection believed to be caused by improperly treated bedsores. The patient was suffering from malnutrition, anemia and dehydration and died the following morning. Shortly thereafter, the beneficiary succumbed to sepsis. The SNF had been under a warning by state regulators for sub-standard wound care. An HHS-OI agent along with a Connecticut State Police investigator were dispatched. Their investigation led to Hillcrest Healthcare Inc. pleading nolo contendere to state manslaughter charges and settled false claims with the USG for \$750,000 and the company was excluded from Medicare and Medicaid programs.

The Government alleged in its investigation that, in addition to quality of care problems relating to the death, there were serious quality of care problems for many other patients in the care of Hillcrest. These problems included severe pressure sores and pressure ulcers, dehydration, weight loss, inadequate staffing, and failure to follow plans of care.

The Connecticut Department of Public Health (DPH) entered into a Consent Order with Hillcrest that required Hillcrest to surrender its nursing home license within 150 days and to pay a civil penalty of \$200,000. In early 2005, Hillcrest entered a plea of nolo contendere in state court to Manslaughter in the Second Degree arising out of the death of the resident discussed above. Hillcrest paid a \$10,000 fine related to its state criminal plea. Hillcrest also paid double damages on a portion of the services billed to Medicare and Medicaid for various nursing home patients, as well as civil penalties, in the total amount of \$750,000 and was permanently excluded from the Medicare and Medicaid programs.

Connecticut U.S. Attorney O'Connor stated; "The egregious quality of care problems found in this case were inexcusable, our elderly population relies on the Medicare and

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Medicaid programs to help care for them in their old age. Nursing home owners and operators should be on notice. If you bill Medicare and Medicaid for essential services, such as turning patients, feeding them and keeping them properly hydrated, and those services are not provided, or are so deficient as to be virtually worthless, we will prosecute you for fraud, and will seek to recover multiple damages and penalties.”¹

False Claims Act: How does this relate to quality?

What factors can trigger a look from investigators? All too often, state survey reviewers conduct on-site audits at facilities and submit reports. There are statements of deficiency issued that in the past were largely unenforced. Minimal fines, sometimes as low as \$1,000 to \$3,000 were handed out from the state and it appears that this simply became a cost of doing business for certain facilities. Recently, there has been movement to enforce deficiencies using Civil Monetary Penalties under both state and federal law.

The False Claims Act offers a powerful tool for the federal government to deter fraud and modify behavior in the healthcare system. This law allows for severe penalties, treble damages and stiff penalties, from a range of \$5,500 to \$11,000 per claim. It has become the contention of prosecutors that a false claim can be charged if the facility has not met its obligations to the beneficiary to provide at least the minimum standard of care. The government has an expectation that for a daily rate, the patient will be cared for, fed, turned and bathed. Where this obligation is not met, it can give rise to a false claim action.

The federal government will generally only intervene if there has been a serious breach of care or subsequent death stemming from lack of care. In most instances, the government will intercede where there is a long-standing pattern of ignoring state survey deficiency findings and there is imminent patient harm. Where no substantial corrective action is taken by a facility over a period of time, and claims are still made, many prosecutors feel that the conduct gives rise to violation of the False Claims Act.

Emerging focus areas for regulators and enforcement agencies include quality of care, poor standards of care enforcement action, administrative sanctions, civil monetary penalties, termination of provider agreements, and provider exclusion. Other issues that have been the focus of enforcers have been medically unnecessary procedures, proper credentialing of medical personnel, and lack of response to survey findings.

Quality of Care issues can and have triggered federal False Claims Act charges in a number of venues. Lack of response to deficiency findings can bring the attention of both the state and the federal regulators or law enforcement agencies. There is tremendous exposure for failure to act on the safety or patient care deficiencies.

¹ CT U.S. Attorney Press release, dated May 18, 2005, <http://www.usdoj.gov/usao/ct/press.html>

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In 2002, the Centers for Medicare and Medicaid (CMS) made Quality of Care the Eighth Scope of Work. CMS initiated a quality initiative, which focused on nursing homes, home health services and hospitals. CMS published quality measures to bring focus to expectations of quality in health services.

Lack of proper wound care is a growing problem for our senior citizens. State Surveyors have give countless warnings, only to return to find that no significant changes were made, leaving patients at risk.

Most facilities can avoid any federal action by adhering to safety requirements, and meeting standards of care. If there are deficiencies cited, a corrective action plan with appropriate follow- up can keep the regulators satisfied and patient care at an acceptable level. It is important to understand how quality measures are defined and reviewed by your organization.

Provider Quality of Care Issues

In Alabama, a psychologist allowed unsupervised counseling of patients by unlicensed and unqualified graduate psychology students. The psychologist was sentenced to 33 months in prison and paid a \$1.8 million fine.

In Connecticut, a skilled nursing facility fire killed 18 patients after an unsupervised psychiatric patient lit sheets on fire. The facility was a mixed use Medicaid-funded SNF with a combination of geriatric patients, psychiatric patients, and HIV/AIDS patients. In this case, a 22 year old patient was housed with a geriatric, non-ambulatory patient. On the overnight shift there was no specialized nursing staff. In this matter, the suspect patient was found incompetent to stand trial.

In action by the OIG, a nursing home was excluded for 5 years for failing to properly supervise a patient. In this matter, an Alzheimer's Patient was found dead outside the SNF.²

A medical center was cited by OIG and the U.S. Attorney's Office for conducting and billing for unnecessary cardiac services. As a result of poor quality healthcare, the Redding Medical Center in Redding, CA was excluded from federal healthcare programs for 5 years. Redding Medical Center was divested from its holding company.

In another enforcement action, a Pennsylvania skilled nursing facility was investigated after a death was caused due to failure to maintain blood level monitoring. The SNF was charged with billing for substandard services and settled for \$90,000 under the False Claims Act.

In a case focusing on a lack of quality care, Raytel Cardiac Services entered into an

² Source: OIG Semiannual Report, April-September 2004, <http://oig.hhs.gov/publications/semiannual.html>

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\$11.5 million settlement for services not rendered. In this matter, in the interest of speed and volume of services, this cardiac device monitoring service failed to render three separate tests by telephone as pacemaker patients called in to have the device tested. The company fell into a practice of taking only two readings rather than the specified three readings to assure the device was properly working after the test was completed. This shortcut rendered the patients at risk of a failed device. .

Over a four-month period, dozens of DME suppliers servicing Florida were found to have billed for thousands of patients in south Florida that had limbs amputated. The bill for \$122 million was paid by Medicare. According to the *Miami Herald*, more than 21,000 seniors needed prosthetic arms and legs. An investigation into the high billing found that those beneficiaries had all their limbs, never had surgery, and never had contact with the companies. The federal judge in the matter publicly denounced the Medicare contractor for allowing such sums of money to be paid without verifying the outlandish claims.³

Recent reports from South Florida indicate that a scheme involving the use of homeless HIV/AIDS patients has surfaced. According to the *Miami Herald*, recruiters for clinics seek potential patients at homeless shelters and drug treatment clinics. Taken by van, the patients are paid \$100 to \$300 in cash for every sitting in the clinic. While at the clinics, the patient is injected with drugs. Each injection is billed for as much as \$6,000 per visit. Recently, Medicare has blocked more than \$200 million in claims and suspended more than 20 providers believed involved in this costly scheme.⁴

Pharmaceutical Fraud

There have been a series of pharmaceutical investigations that have focused attention on industry practices relating to Medicare and Medicaid pricing, free samples, and sales and marketing approaches to increase market share. Bayer, Pfizer, AstraZeneca, GlaxoSmithKline, TAP Pharmaceuticals have all come under scrutiny for violations of the False Claims Act and/or the Prescription Drug Marketing Act.

In a recent Bayer case, it was found that the company was relabeling Cipro and Adalet CC, and distributing the drugs to an HMO for reduced cost and hiding that agreement from the government. The purpose was to reduce the amount of drug rebates returned to state Medicaid programs. In this case Bayer failed to provide the U.S. and states with the best price. A settlement was negotiated with the U.S. Attorney's Office in Massachusetts for \$257 million settlement. In another matter with Bayer, a \$14 million settlement was negotiated for the falsification of documents regarding wholesale prices of Hemophilia and AIDS drugs.

A similar scheme was uncovered in North Carolina and Pennsylvania, where GlaxoSmithKline (GSK) failed to report the best price to states for Flonase and Paxil. As a result, GSK entered into an \$88 million settlement for failing to accurately report prices

³ Source: Miami Herald, May 10, 2005.

⁴ From Miami Herald, June 30, 2004.

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to CMS.⁵ The case GSK led to the settlement for fraudulent reporting of best price on sales of Paxil and Flonase to minimize Medicaid rebate obligations. Similarly, Pfizer entered into a \$49 million settlement in Texas, for failure to avail “best price” for Lipitor to Medicaid program.

In a matter against Parke-Davis, a settlement of \$430 million settlement for off-label promotion of Neurontin, suggesting unapproved uses. Parke-Davis was charged with Food, Drug & Cosmetic Act violations. In this matter, there were concerns for the safety of the patient, without FDA approval

Zeneca and AstraZeneca Pharmaceuticals LP repaid the US Government nearly \$355 million for its improper marketing and pricing schemes of a prostate cancer drug named Zolodex. AstraZeneca was found to have induced physicians with free samples and conspired with these practitioners to bill the government, conspired to adjust prices and caused higher billing of Medicare and Medicaid. The corporation was also found to have avoided Medicaid drug rebates. The corporation was placed under a five-year Corporate Integrity Agreement. AstraZeneca entered into the settlement in Delaware for the practice of enticing urologists with free samples of Zoladex, a prostate cancer drug.

In a similar case, TAP Pharmaceuticals, a competitor in prostate cancer treatments, entered into a settlement with the U.S. Attorney in Massachusetts for \$860 million for marketing practices that included unrestricted educational grants, and provided free samples, later billed to federal healthcare programs by urologists.

What’s Next?

Future priorities for enforcers will include attention to potential fraud with pharmaceutical manufacturers and distributors, pharmacy benefits managers, the prescription drug benefit, under-filling and dilution of drugs and pain management clinics.

With the added anticipated cost outlays for the 2006 Medicare prescription drug benefit, it is expected that the marketing tactics of pharmaceutical manufacturers, distributors and benefits managers will require close scrutiny. CMS, enforcement agencies, prosecutors, regulators and CMS contractors are all preparing for the expected rise in fraud schemes with the introduction of the Prescription Drug Card program. Since announced, there have been a rising number of complaints from senior citizens about unscrupulous entities and individuals. Investigations have been launched into predatory sales practices, misrepresentation of the Rx card program, bilking seniors of money and impersonation of Medicare representatives. While the Medicare Modernization Act was intended to enhance services for those in need of healthcare services, entities are being created to take advantage of the growth and are looking for opportunities to defraud the federal healthcare programs of dwindling resources.

⁵ Simmons, John, Why Do Drug Companies Fear Michael Sullivan? [Fortune Magazine](#), 10/13/03.

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The importance of insuring quality of care by providers, hospitals, laboratories and long-term care facilities is vital to the solvency and ability to treat and pay for beneficiaries in years to come. While quality of care cases are time consuming, the aggressive use of the False Claims Act will continue to address the most egregious cases of patient harm or patient death. Prosecutors admit that it is often difficult to quantify the damages and difficult to assess the loss to the healthcare program. It is vital that the regulators, enforcers and prosecutors work together to address the rising tide of quality of care issues in our healthcare systems.

About the authors . . .

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Ms. Vacca has over 20 years experience in the acute care hospitals and outpatient settings that included clinical and administrative positions. Sheryl has lectured extensively throughout the US. She is a registered nurse and holds a master's degree in administration. Sheryl can be reached at svacca@deloitte.com.

Authors Note:

The article was drawn from many sources and constitutes an overview of the state of quality of care fraud in the U.S. It is not meant to be all-inclusive. Sources have been incorporated into the paper including information from the public domain, generally from the U.S. Department of Health and Human Services, and other commercial sources.