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Editor's Column

HEALTHCARE REFORM: Will Anything Survive?

It was your editor's intention to utilize this space to discuss the likelihood of any healthcare reform provisions relating to long term healthcare to emerge from the current battle in the nation's capital. As most of you know, the various bills still technically alive contain several significant provisions affecting long term healthcare.

Recent events suggest this is a poor idea: When the dust settles, "Of Counsel" will devote a special issue to whatever emerges (if anything) that centers on this topic. In the meantime, we've become intrigued by the convergence of recent congressional amendments to the False Claims Act and the re-emergence of Corporate Compliance. It is hardly surprising that the only major elements affecting long term care to remain from the
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THE COMPLEX AND CONFUSING FALSE CLAIMS ACT/CORPORATE COMPLIANCE MESS: How to Deal With It

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and

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Case Study:

ABC Nursing and Rehabilitation Center in Pottsville is a 5-Star nursing facility, well known for admitting and caring for difficult patients discharged from nearby acute care hospitals. Amy Pierce is a CNA recently employed by ABC; she has been caring for Mrs. Jones, a recent hospital discharge on Medi-Cal, who must be turned in bed frequently in order to avoid or mitigate the development of pressure ulcers. Amy noticed that Mrs. Jones had what looked like the beginnings of a decubitus ulcer on her lower back when she was admitted, and she reported it to Lois Smith, the director of nursing when she discovered the problem. Several weeks after her initial employment at ABC, the human resources director at the facility was reviewing Amy's employment application and noticed discrepancies. Upon checking with law enforcement authorities and the state, it was found that Amy had lied on her job application when she stated she had not been convicted of a crime; it turns out, Amy had
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 current political battle may, indeed, be aspects intended to battle “waste, fraud and abuse” in the healthcare system. That being the case, we have decided to devote this issue entirely to that subject.

We hope it makes good, if scary, reading.

*Michael A. Manley, Esq.,
 Editor*

About Diepenbrock Harrison

Diepenbrock Harrison has roots in Sacramento, California’s capital, which date back to the 1800s. Our practice focuses on acquisition, development and protection of property, permits and business opportunities, and resolving regulatory disputes. We are active in the legal aspects of the healthcare arena, and specialize in representing senior care and living providers. We are members of Aging Services of California and the California Association of Health Facilities.

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three shop-lifting convictions within the past three years. The HR director conferred with ABC’s administrator and it was determined to discharge Amy for falsification of her employment application. Several days before that decision was arrived at, Amy noticed Mrs. Jones’ skin ulcer was growing alarmingly. Ultimately, Amy was called in to the administrator’s office and was discharged. Several weeks later, accompanied by Sam Blather – an employment law plaintiff’s attorney - she reported instances of substandard care of Mrs. Jones at ABC to the local U.S. Attorney’s office. Thus, she became a “relator”.¹ The U.S. Attorney undertook an investigation of ABC pursuant to the federal False Claims Act. Later, on Blather’s recommendation, Amy retained John Easy, an attorney noted in Pottsville for the representation of *qui tam relators* – or “whistle blowers”.

Sound familiar? Such instances are likely to proliferate thanks to amendments to the False Claims Act approved by Congress five months ago, particularly when coupled with a soon-to-become-mandatory Corporate Compliance program mandate.

Here’s the background, plus some suggestions on how to avoid becoming an “ABC Nursing and Rehabilitation Center”. A brief history may be in order:

The 2000 Guidance

In 2000, the Office of the Inspector General of the Department of Health and Human Services (“OIG”) published *Compliance Program Guidance for Nursing Facilities*. The OIG’s guidance, framed as avoidance of fraud and abuse in the Medicare and Medicaid programs, was intended to assist all nursing facilities, large and small, with developing effective compliance programs, irrespective of location or status (e.g. for-profit and not-for-profit facilities). The guidance provides essential ingredients for a successful compliance program, as well as several specific areas of risk for nursing facilities, including quality of care, employee screening protocols, residents’ rights, billing, cost reporting, and vendor relations. To ensure compliance with quality of care and other standards, nursing facilities are encouraged to

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formulate comprehensive health care plans for every beneficiary, self-report incidents of abuse and neglect, establish fair admission policies, avoid patient abuse, avoid improper billing practices, avoid unlawful kickback activities, and maintain adequate documentation at all times. The enforcement “stick” for violation is the federal False Claims Act, a Civil War statute (1863) originally intended to prevent war profiteering but employed over the past several decades to prosecute fraud and abuse by healthcare providers.

The 2008 Supplemental Guidance

In the late summer of 2008, the OIG published *Supplemental Compliance Program Guidance for Nursing Facilities*², which centers substantially upon clinical quality of care issues. The 2000 and 2008 guidance documents collectively offer guidelines for developing, implementing, and evaluating a compliance program for a nursing facility, and are intended to "facilitate discussions among facility leadership regarding the inclusion of specific compliance components and risk areas." With a heavier emphasis on quality of care, the supplemental guidance provides three areas to be addressed in all compliance programs: (1) quality of care risks; (2) submission of inaccurate claims risks; and (3) anti-kickback liabilities. With regard to quality of care, the OIG in 2008 identified five sub-areas: (i) sufficient staffing, (ii) the development of comprehensive care plans for each patient, (iii) medication management, (iv) appropriate use of psychotropic medications, and (v) promotion of resident safety.

Inadequate staffing is defined as improper staff-to-resident ratios, inappropriate skill mix among the staff, and problems arising from staff scheduling patterns, high staff turnovers, and a host of disciplinary matters, all identified as problematic and requiring close attention by nursing facility managers. The OIG also identified a "significant percentage of resident care plans (which) did not reflect residents' actual care needs." Therefore, the supplemental guidance cautioned against a care planning process which excludes physicians and other disciplines from the planning process. In addition, reports of improper medication management prompted the OIG to place this issue high on the list of problem areas it wanted addressed in compliance programs. Lastly, resident safety with respect to staff/resident altercations and resident-to-resident encounters was also emphasized by the OIG..

To develop a compliance programs that conforms with the OIG's 2008 supplemental guidance with regard to inadequate staffing, facilities are "encouraged to assess their staffing patterns regularly to evaluate whether they have sufficient staff members who are competent to care for the unique acuity levels of their residents." This is achieved by evaluating "on-the-floor" staffing using actual payroll data reflecting hours worked as opposed to evaluating "on-paper" staffing using scheduling data. To ensure resident care plans reflect residents' needs, compliance programs should include regular care plan meetings and ensure that clinical assessments are completed in advance of those meetings. With regard to medication management, compliance programs must ensure medication protocols that advance patient safety through prompt discovery and remedy of medication irregularities.³ Finally, to protect against resident abuse, compliance programs must provide for employee screening, as well as assessments of residents' aggressive behavioral tendencies. To ensure resident safety, the OIG suggests confidential 24 hour reporting as a component of the facility's compliance program.

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With respect to submission of accurate claims, the OIG's supplemental guidance identified four risk areas with regard to claim submission. These include case mix, or inaccurate reporting of Resource Utilization Group ("RUG") rates resulting in upcoding of claims; (2) overutilization of therapy services; (3) reimbursement of excluded contractors; and (4) restorative services that are "so wholly deficient that they amounted (sic) to no care at all". Facilities must review case mix data regularly to maintain accuracy. With regard to therapy services, the OIG supplemental guidance advised nursing facilities to "develop policies, procedures, and measures to ensure residents are receiving medically appropriate therapy services." Nursing facilities should request that all therapy contractors provide contemporaneous and complete documentation. In addition, the nursing facility might elect to interview the resident and the resident's family to determine whether the therapy services are in fact received by the resident. Facilities must implement procedures to ensure all therapy services rendered are of an appropriate quality and level, and that such services are in fact rendered. Finally, the OIG recommended compliance programs include regular staff interviews, medical record reviews, attending physician consultations (as well as consultations with the medical director and any consulting pharmacists), and observation and documentation of care delivery.

With respect to anti-kickback issues, the OIG addressed the supply of free goods and services, service contracts, discounts or swapping, hospices, and reserved bed payments. Examples that raise potential issues include the provision of supplies or consulting services offered by a pharmacy or laboratory, or computers or software, and which provide an independent value to the facility. Arrangements that do not fall under an applicable safe-harbor condition potentially subject a nursing facility to liability. Swapping arrangements involve the acceptance by the facility of a low price from a supplier covered by Part A *per diem*, in exchange for which the facility refers other federal health care program business such as Part B business that is excluded from consolidated billing, for which the supplier can directly bill Medicare or Medicaid. Nursing facilities are not the type of entity particularly prone to swapping, unlike clinical laboratories, ambulance providers, and durable medical equipment suppliers. Finally, requesting or accepting benefits from a hospice may subject the facility and the hospice to liability under the anti-kickback statute if those benefits might influence the facility's decision to do business with the hospice.

To summarize, a corporate compliance program is seen by the OIG as a comprehensive strategy to ensure a facility complies with laws and regulations pertaining to its business and clinical activities. An effective corporate compliance program (1) addresses business and clinical activities and their consequent risks; (2) educates persons whose jobs have a material impact on the activities of the facility; (3) encourages employees and others with knowledge of the facility to self-report; (4) includes auditing and reporting functions designed to measure the effectiveness of the program; and (5) contains enforcement and discipline components to ensure compliance is taken seriously.

The False Claims Act Amendments of 2009

Although the need for the adoption and enforcement of corporate compliance programs has been on the regulatory books since 2000, events in the last two years have accelerated their

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importance to healthcare providers, particularly nursing facilities. First came the 2008 supplemental OIG Guidelines which, for California-based nursing facilities, sound very much like the state's Title 22 in federal form.

Then late last year Congress amended the False Claims Act ("FCA"), significantly broadening the law's coverage. From the outset, the statute has provided a cause of action for the government against a defendant who submits a "false or fraudulent claim" or who "knowingly uses a false record or statement to get government approval of a false or fraudulent claim". These words have appeared in the FCA since its original enactment in 1863. The question arises, however: Are long term care providers in violation if they seek federal payment for services which, although they were rendered, fall short of the accepted standards of care? This has become known among prosecutors as the "worthless services" theory.

Without going into legal detail, court cases have covered the waterfront in terms of their interpretation of this issue. The explicitly-stated purpose of the 2009 amendments to the FCA ("The Fraud Enforcement and Recovery Act of 2009", Public Law No. 111-21, 123 Stat. 1617) is to correct court decisions which "have limited the effectiveness" of the FCA. Congress made sure in its enactment that in the future anyone who makes a false record or statement which is material to a government claim will have violated the law. In a major stiffening of the FCA, Congress added language making it clear that anyone who "retains any additional overpayment" of a government claim will become liable.

At the same time, federal lawmakers retained the rather harsh financial penalties for violation of the FCA: treble damages, plus individual per claim penalties of up to \$11,000. In short, the juxtaposition of the 2009 FCA amendments with the OIG's renewed emphasis upon Corporate Compliance is enough to make any business in receipt of government funds sit up and take notice.

2010 Healthcare Reform Bills

To cap it all off, this year the House and Senate each passed healthcare reform legislation which differed in many respects but contain identical provision which, if enacted, will mandate Medicare and Medicaid providers to establish and enforce corporate compliance programs. (The OIG's 2000 and 2008 guidance was recommended, not required.) President Obama's version of healthcare reform, released on February 22, 2010, copies the Senate-passed provision insofar as it mandates Corporate Compliance programs. It hardly needs to be added that all three healthcare versions contain enhanced funding for the rooting out and prosecution of "waste, fraud and abuse". In the authors' opinion, these "waste, fraud and abuse" amendments are likely to become law regardless of the ultimate fate of broader healthcare reform.

Conclusion

It is our experience that the overwhelming majority of skilled nursing facilities and other Medicare and Medicaid providers have adopted corporate compliance programs based, at least, on the 2000 OIG recommendation, and most have now folded the 2008 clinical pronouncements

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into their programs. However, just how well facilities have enforced their compliance programs remains open to question. It seems obvious with the renewed emphasis by the federal government upon pursuing False Claims Act prosecutions ... both civil and criminal ... that facilities must look to fully implementing their compliance programs. Facilities need to ask themselves: Do we have an active corporate compliance officer? How about a hot-line to report potential violations? Do we conduct regular employee education in-service programs on compliance issues, and do we document employee attendance? Do we conduct mock surveys intended to test clinical compliance in our facilities? Is there regular monitoring in our facilities of the false claims and clinical issues that federal regulators will be looking for? Who does that monitoring?

If your answers to any of these hot-button questions give you pause, it would be wise to revisit this tired, old ... but now re-energized ... issue of Corporate Compliance.

Diepenbrock Harrison attorneys will be happy to work with you in evaluating your corporate compliance program, recommending modifications if needed, and assisting you in implementing your program.

¹ A “relator”, or more properly a “qui tam relator” is defined as a private party who can sue someone he or she believes is defrauding the government on behalf on himself/herself and the United States. The suit must be filed under seal and served upon the government, which then has a period of time to investigate the relator’s complaint. If the government decides to pursue the case, it has the primary responsibility for prosecuting the action, but if it declines to do so the relator may continue the action on behalf of the government. In either case, if the plaintiff succeeds, the relator can reap substantial financial benefits in the form of significant percentages of the ultimate recovery.

² *OIG Supplemental Compliance Program Guidance for Nursing Facilities*, 73 Fed. Reg. 56832, 56836 (Sept. 30, 2008)

³ The OIG also notes the potential conflict of interest and anti-kickback concerns when the consultant pharmacist is associated with the institutional pharmacy used by the facility.

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Diepenbrock is an associate member of Aging Services of California and The California Association of Healthcare Facilities.

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