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Quality of care and corporate compliance—Perfect together!

By David Hoffman

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When I think of corporate compliance and ensuring that quality care is provided, I am reminded of the time when the state of New Jersey introduced its new slogan; “New Jersey and You, Perfect Together!” From my perspective, quality of care and corporate compliance are perfect together. Of course, not every provider agrees with me, so I will attempt to delineate what is intended by meaningful quality assurance that ensures the delivery of quality care and how compliance fits into that model.

Quality versus failure of care

The first question, naturally, is “What is quality care?” Isn’t “quality” a purely subjective term? For example, in a consumer-driven care delivery model, as long as a personal care aide appears in a timely fashion, a consumer may believe that he or she is receiving good quality care. The actual care rendered, however, has not been evaluated to see if it meets professionally recognized standards, which is typically how quality is measured. From a regulators perspective, quality may be associated with meeting the letter of a regulation without regard to clinical outcomes, thereby frustrating health care providers who are delivering good care but get cited for deficiencies, regardless of that fact.

It is instructive to clearly define what the so-called “quality-of-care” prosecutions (federal) are all about in an effort to establish the parameters for our discussion and to avoid care-driven investigations. While all health care fraud cases have the potential to impact on quality care, the better descriptor of these cases is not “quality of care,” rather it is a “failure of care.” These cases are not about the ordering of unnecessary services or entities paying kickbacks in exchange for business; they are

about a wholesale failure of care delivery to vulnerable populations.

Simply stated, failure of care means that health care providers knowingly failed to deliver care that met professionally recognized standards on a relatively routine basis, in effect delivering worthless health care services to frail and vulnerable adults.¹ These cases evidenced providers’ systemic failures in identifying the needs of residents and providing a timely response to clinical conditions that were clearly avoidable, if systems that checked care-related issues had been in place and facility staff had been paying attention.

Typically, there was no evidence of kickbacks or upcoding or the ordering of unnecessary services. Instead, care was rendered that was tantamount to no care at all: (a) nursing home residents developed pressure ulcers as a result of not being adequately fed, hydrated, or repositioned; (b) hospital patients were improperly restrained; (c) personal care home residents did not receive adequate nutrition; (d) nursing home residents did not have their pain levels evaluated or managed; and (e) diabetic residents did not have their blood glucose levels monitored, leading to severe hypo- or hyperglycemia.² These are the failures that government enforcement has been premised on, not a misjudgment, mistake, or improper financial relationship.

Government investigative strategies

A useful starting point for a defensive strategies discussion can be found in the way the government pursues investigations in failure-of-care matters. Typically, a government investigation starts after a provider has been identified as delivering substandard care as evidenced by adverse clinical outcomes to vulnerable residents. A common defense is that staff was following the facility’s policies and procedures so “we did the best we could.” When were the policies updated? What are the policies based on? Are they evidence-based? Blindly following

policies and procedures that are not tailored to meet the individual needs of a resident offers no protection from liability for staff and the organization.

Next, the government will review prior survey findings to establish knowledge of the problem and a pattern of non-compliance. In many instances, the very same care issues surface from survey to survey, thereby questioning whether the provider's plan of correction that was submitted to the surveyors (which had the effect of continuing participation in the Medicare and Medicaid programs and continued payment) actually was implemented or effective. A common request by the government will be for documents related to the plan of correction in order to validate whether it occurred or not. If a plan of correction is found to be false or fraudulent, the provider's liability is clear and actionable. It is also critical for providers to do root-cause analyses on care deficiencies to avoid having the same issues reappear six months later. Therefore, a compliance unit that has some oversight function for plans of correction may limit exposure and also ensure meaningful change in a potentially flawed care-delivery system.

Also, even if an investigation does not lead to civil or criminal penalties under the fraud statutes, including the federal False Claims Act (an enforcement tool commonly used by government attorneys), the HHS-Office of Inspector General (OIG) can exclude health care providers from participation in Medicare, Medicaid, and other state health care programs, independent of a fraud action. Typically, this would sound the death knell for a health care provider, because it would not receive reimbursement from government health care programs such as Medicare, Medicaid, and others. As such, waiver of this exclusion authority is a provision found in most health care settlements with the federal government.

The OIG has permissive exclusion authority when services are rendered that are "of a quality which fails to meet professionally recognized standards of health care" [42 USC section 1320a-7(b)(6)(b)]. The OIG can also take exclusion actions based on the referral from a Quality Improvement Organizations (QIOs) [Section 1156 of the Social Security Act]. Interestingly, the most recent Government Accounting Office (GAO) report³ addressing QIOs calls for the Centers for Medicare and Medicaid (CMS) to strengthen the QIO nursing home improvement initiative by securing agency access to nursing home-level data, increasing evaluation of QIO effectiveness in greater detail so the most effective interventions can be broadly adopted, and focusing more QIO assistance on low-performing nursing homes. The GAO report found that the QIOs did not target poor survey

performing facilities for assistance. Instead, the QIOs worked with willing providers instead of poor-performing providers. The QIO exclusion referral process has focused solely on individual physician-related matters, but OIG made no exclusions in fiscal year 2006 as a result of a QIO referral. This

strikes me as problematic, and perhaps QIOs view their role as simply assistive in nature and not enforcement driven. From a patient safety perspective, these roles need to be clearly defined, because health care practitioners who harm patients/residents should be excluded from federal health care programs.

Owners of health care providers who choose profits over care needs have been prosecuted both criminally and civilly. Because failure of care is more a result of flawed systems (as opposed to intentional or reckless acts), these failures can be eliminated if there is an effective compliance program that is embraced at all levels of an organization.

Compliance as a means of defense

Interestingly, entities define compliance in many different ways. Historically, compliance was a claims-driven process with the thinking being that "We are compliant if we are billing properly." Billing appropriately is an important component in ensuring compliance with applicable laws and regulations, but that is not the end of the discussion. Health care providers deliver services and must ensure that the health care service delivered is compliant with all laws and regulations as well. The bill has to be supported by the delivery of health care services that meet all regulatory requirements. Does hiring qualified people (i.e., properly credentialed professionals) ensure compliance? Can a health care provider take comfort in knowing that its staff is well-educated, as evidenced by their credentials, without regard to training and evaluation of competencies and performance? From my perspective, the answer is an unequivocal no.

Meaningful quality assurance that is integrated into a corporate compliance program can identify and address these issues. The role of



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compliance is not to second guess competent staff. It is to support staff to ensure that care that meets professionally recognized standards is being delivered and supports the claims being submitted to third-party payers.

The establishment of policies and procedures that set forth the current best practices as to how care is to be delivered is critical to success. These policies should be evidence-based and provide state-of-the-art care delivery approaches. A good example relates to care associated with addressing falls. As we know, falls can have a devastating effect, both physically and psychologically, on frail older adults. The proactive assessment of residents who are at risk for falling, coupled with multiple preventive and post-fall interventions, has gone a long way in reducing severe outcomes associated with a fall. That is where the compliance side comes into play. Trending data, resident outcome review, and meaningful quality improvement should not be the sole responsibility of a risk manager or clinical operations director. These are organizational functions and a responsibility that should be shared and integrated into the compliance program. Clinical best practices can be developed and shared throughout the organization. On the flip side, if a care protocol is not successful, corporate compliance, in conjunction with quality improvement, should be able to identify this issue and respond appropriately (i.e., revision of the policy, training on the new policy, evidence that everyone is following the policy, and monitoring that the policy is effective).

The future: Financial incentives/reimbursement and quality care


A recent GAO report related to nursing homes concluded that financial penalties were not an effective tool to improve care and that other available sanctions, such as directed plans of correction, temporary management, and exclusion were rarely utilized.⁴ The GAO found that penalties did not substantially change the behavior of repeat offenders. A number of different reasons have been attributed to this fact. The most obvious reason is that the average fine was \$350 per day. This penalty amount will never be a successful behavior modification tool and instead has been and will continue to be viewed as a minor cost of doing business. Financial penalties can be effective only if they are large enough to compel behavior change.

CMS has recently notified providers that it will no longer pay for preventable occurrences, such as pressure ulcers and infections in the hospital, starting October 2008. Is it really far from the realm of possibility that this will extend to other institutional settings and other clinical conditions? Will the link of outcomes or avoidable clinical conditions to payment finally put the quality initiative into overdrive?

I firmly believe that this policy will go where no penalties, fines or prosecutions could take us. The government may finally have hit the right button to compel quality care, at least in those areas where it is obvious that poor care was rendered.

Government enforcement activities will continue to focus on the quality of the care that is rendered by providers and paid for by the government. The best approach to avoiding the government's scrutiny is to have an effective compliance program that integrates care and care delivery processes. We all recognize that mistakes occur and, on occasion, may lead to adverse consequences. But if we follow the motto that compliance and quality are perfect together, we can go a long way in reducing these mistakes and certainly avoid a full blown government investigation and prosecution, because an effective compliance system will have identified and responded to care concerns in a timely fashion. ■

1 See e.g., United States ex rel. Lee v. Smithkline Beecham, Inc., 245 F.3d 1048 (9th Cir. 2001); United States ex rel. Mikes v. Strauss, 274 F.3d 687, 703 (2d Cir. 2001); c.f. United States v. NHC Healthcare Corp., 163 F. Supp. 2d 1051 (W.D. Mo. 2000). In the criminal context, see United States v. Wachter, et al., No. 4:05 CR 667 (Magistrate's Report denying defendants' pretrial motions) where the Court discussed extensively the various legal theories of liability associated with failure of care matters.
2 For a listing of settled failure of care cases in the Eastern District of Pennsylvania that alleged these types of care issues, go to www.usdoj.gov/usao/pae/Documents/elderabuse.htm.
3 Nursing Homes: Federal Actions Needed to Improve Targeting and Evaluation of Assistance by Quality Improvement Organizations, United States Government Accountability Office, Report to Ranking Member, Committee on Finance, United States Senate, May, 2007 (GAO 07-373)
4 Nursing Homes: Efforts to Strengthen Federal Enforcement Have Not Deterred Some Homes from Repeatedly Harming Residents, United States Government Accountability Office, Report to the Ranking Minority Member, Committee on Finance, U.S. Senate, March 2007 (GAO 07-241)

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