



Notes

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The Quality/Compliance Nexus: Moving to Programmatic Integration

The health care industry has now finally reached the stage where the risks of false claims liability for improper claim submission, whether to the public programs or private insurers, are now widely recognized. What is less well understood is the growing connection between statutory and regulatory controls for quality and false claims, as well as the increasing interest by health care law enforcement in the quality of care delivered. To the extent that ‘compliance’ has been seen primarily as risk management of the billing function, quality issues must now also be taken into account for a meaningful and comprehensive compliance program. This AGG Note (1) explains the connection between quality and compliance; (2) discusses trends in this arena; (3) identifies under-appreciated controls over quality which already present enforcement liabilities; and then (4) considers some ways in which the linking of compliance and quality efforts in health care can, in fact, strengthen both.

The New Quality Era

Traditionally, to address quality, both health care policy and regulation have focused on three aspects of the care delivery system: (1) inputs – controlling for the context within which care will be delivered, like in licensing regulations and certification requirements; (2) process – assuring the appropriateness of the steps in delivering the care; and (3) outcomes – addressing whether the efforts in providing care improve or assure the results of the care for the patient. This analytical construct, which was first enunciated in the 1960s, has not gotten health care quality to optimal levels.

Today, although some decry the absence of a clear, common policy definition of good quality, it is generally accepted that there are three fundamental aspects to quality problems: (1)

underuse – not giving the patient enough of what he needs; (2) overuse – giving the patient too much of what he needs; and (3) misuse – giving the patient the wrong thing.

With the publication of the Institute of Medicine study “To Err is Human”, new attention was focused on medical errors which generated an explosion of interest in patient concerns. The second study, “Crossing the Quality Chasm,” announced principles which, if brought to bear widely throughout health care, could change the quality of care delivered. Taken together, there is no question that there is new attention to the failure of the American health care system to deliver those levels of quality which most people would consider acceptable and many lay people simply assume is present.

The information here is presented as a service to readers. It is not intended as legal advice. We have attempted to provide information which is up to date, but rules often change. No one should rely on this information alone and should obtain current, informed legal guidance with regard to the issues contained herein. The author makes no representations, nor guarantees regarding the contents of the information contained herein.

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A Parallel Compliance Era Emerges

While these quality policy initiatives were rising to the fore, the new era of compliance programs was also developing. The initial impetus for compliance plans was the federal sentencing guidelines, enacted by Congress to curb the discretion of a federal judiciary seen as too liberal. The sentencing guidelines are formulaic and prescriptive. They establish the range of prison time for a criminal penalty and then they indicate what will be considered mitigating and aggravating factors that determine the extent of prison time. One of the mitigating factors is whether the enterprise has in place a compliance program which generally tries to prevent violating behavior. Compliance plans and programs are voluntary. The motivation to put one in place comes from the risk aversion of the potential criminal.

In health care, the advent of corporate compliance programs was launched with the government's settlement with National Medical Enterprises which involved not only a guilty plea but a government imposed compliance plan in the form of the first 'Corporate Integrity Agreement'. This agreement was designed to impose internal programs on the company which likely would prevent the kind of billing problems which had led to the prosecution in the first place. Thereafter, the Office of the Inspector General took an even more activist stance, announcing in Model Compliance Guidances focused on specific aspects of the industry, how companies might adopt policies, procedures and programs that would prevent violating problems before they occurred, would actively seek to identify problems which had developed and would rectify them with repayments or voluntary disclosures.

The Model Compliance Guidances are focused primarily around issues of billing and kickbacks, but they do go beyond that. Some observers argue that they establish the state of the art for risk management of the billing functions. Yet, all they can actually do is reveal the

government's current understanding of the sector of the industry addressed, and highlight some concerns. They are not mandatory. They do not state the only way to comply. In fact, the real significance of a compliance program is not its relationship to the sentencing guidelines, but the likelihood it can actually lower the risk that problems will arise. Thereafter, the provider is expected to come forward and repay monies improperly received.

The Guidances now address eleven (11) separate aspects of the health care industry in chronological order of their publication beginning in 1998: hospitals, clinical laboratories, home health agencies (HHAs), third party billing agents, durable medical equipment and prosthetics and orthotics suppliers (DMEPOS), hospices, Medicare +Choice programs (the only context in which a compliance plan is mandatory), skilled nursing facilities (SNFs), small and solo physician practices, ambulance suppliers and the pharmaceutical industry. They all incorporate common features: having a compliance officer, establishing corporate governance involvement in compliance, articulating policies and procedures, establishing non-retaliatory mechanisms for employees to report problems, and correcting errors.

Each Guidance includes OIG-identified 'areas of concern'. These areas typically reflect matters on which the OIG has taken action, entered settlements or pursued other enforcement avenues. In some instances the areas of concern reflect issues that may not have yet been the subject of enforcement.

All of the Guidances refer to quality as a government concern generally and state that one of the potential benefits of a voluntary compliance program is improved health care quality. The HHA Guidance refers to a clinical review to be sure the beneficiaries are getting medically necessary and appropriate numbers of visits.

The DMEPOS Guidance refers to the quality of the item for which the claim is submitted as meeting appropriate standards. The Hospice Guidance explicitly addresses the need for a quality assurance program as required in the entity's conditions of participation, but also refers to the timeliness of referral to hospice as a quality issue since late referrals can undermine the value of the hospice benefit. So proper hospice utilization is a compliance issue in terms of how hospices relate to their referral sources, and in particular hospitals.

The strongest statements linking quality and compliance can be found in the Medicare+Choice Guidance and the one for SNFs. The Medicare+Choice Guidance puts strong emphasis on underutilization and quality of care issues to be taken into account in the compliance program. Quality assessment, insufficient numbers of providers, provider licensure and review of quality data are all included in the specifically enumerated risk areas. Similarly, quality of care is a significant component of the Compliance Guidance for SNFs.

In the Physician Guidance, the relationship between anti-kickback violations and quality is addressed with the observation that remuneration for referrals can undermine quality. This Guidance also notes that medical record documentation serves both a quality function and a billing function.

In the Pharmaceutical Industry Guidance the interrelationship between remuneration arrangements on one hand and patient safety and quality on the other are also considered in the risk areas, which include formulary development.

This explicit reference to quality concerns in the Model Compliance Guidances makes it clear that the government expects providers to be integrating some quality functions into their compliance activities. Related topics can be

found in the OIG's Work Plans for 2002 and 2003.

OIG Work Plan Targets

Here, again, there are common misconceptions regarding the significance of an issue appearing in the OIG's Work Plan. The inclusion of a topic, even repetitively, does not mean that everyone engaged in that conduct will be audited, fined or even targeted. Inclusion of an issue in the OIG's Work Plan generally means the OIG has received reports from the field (carriers, intermediaries, investigators) that lead them to believe there are problems afoot with that conduct. Usually inclusion in the Work Plan means the OIG will study the issue more intently with an eye to making recommendations directly to carriers, intermediaries, regional offices and others involved in claims payment or in the form of Advisory Bulletins or Fraud Alerts. Inclusion of an issue in the Work Plan is also a fair warning to the industry that some carriers or intermediaries are finding problems with these issues and likely will audit on their own.

In the 2003 Work Plan at least four issues which arguably reflect quality concerns are included: hospital quality oversight; certification of heart transplant centers; the medical necessity of emergency department diagnostic testing and the medical necessity of allergen injections.

The 2002 Work Plan states more quality-relevant topics. First is hospital privileging which reflects the longstanding concerns of the AMA regarding economic credentialing in hospitals. The OIG has called for comments on how economic credentialing may implicate the anti-kickback statute. See our comments to the OIG on this at <http://www.gosfield.com/PDF/oigv2.pdf>. We address legitimate quality controls over privileging and elucidate how many current hospital tactics undermine quality and implicate the anti-kickback rules. In addition, the Work Plan targets the PRO sanction authority; home

health care quality generally; nursing home quality assessment and assurance committees; family experience with nursing home care; and use of restraints in many settings.

The point is that the OIG, with its authority to sanction, fine, and exclude providers, now considers quality appropriately within its purview. And the OIG is not alone. The Department of Justice has moved in new and creative ways to enforce provider obligations to provide quality care.

Quality in DOJ Settlements

The Justice Department's first sortie into the quality realm took off, as many of its creative enforcement techniques have, out of the US Attorney's Office in the Eastern District of Pennsylvania. Faced with a skilled nursing facility's failures of care as demonstrated in aggravated and serious bed sores, the US attorneys went after the home in a novel way. Having learned that one of the contributing factors in bad bed sores is malnutrition, they fashioned an argument that every day of care paid for by Medicare where the patients had bed sores was a false claim since the obligation to provide the nutrition was implicit in the payment to the SNF. The failure to provide adequate nutrition made every such claim false. In US v. GMS Management –Tucker Inc. (ED Pa 1996), the facility paid \$535,000 dollars in settlement and agreed as part of its Corporate Integrity Agreement to apply the clinical practice guidelines for treatment of decubiti which the government's Agency for Health Care Policy and Research had published a few years earlier. This theory was further applied throughout the country in some 40 or so additional settlements, often as instigated by whistleblowers.

This year in US v. United Memorial Medical Center, a hospital in Michigan pleaded guilty and paid a \$1.05 million fine where a very prolific anesthesiologist on staff performed unnecessary procedures for which the hospital was paid the associated facility fees. The

patients suffered significant complications. The physician himself was criminally prosecuted and convicted.

Jim Sheehan, Assistant US Attorney in Philadelphia, a pioneer in these new enforcement approaches, is interested in a range of quality relevant concerns. Where services are provided in a context of staffing shortages, or where worthless, unnecessary or incorrectly performed services are rendered, the same false claims arguments can be made. He has also focused on clinical research falsifications. He questions situations where physicians enroll their own patients in studies for which they are being paid, believing they do not adequately disclose their involvement and the fact that the patient may get no clinical benefit at all from participating in the trial which could be poor quality. He believes there are significant conflicts of interest in these contexts which he can pursue under both false claims and breach of fiduciary responsibilities theories.

In the pending Tenet-hospital investigations in Redding, California, administrative subpoenas which have already been issued, reportedly threaten the exclusion of physicians for delivering substandard care. Some obligations rest on the nature of the entity. Other quality obligations are created by regulation.

Quality-Relevant Federal Regulation

There are a number of sources of quality-relevant regulations that implicate compliance issues. Some of these involve basic federal regulation of quality as in conditions of participation that hospitals, SNFs, dialysis centers, HHAs and the like must meet to be eligible for payment. Any well organized compliance program will pay some attention to maintenance of compliance with those conditions. Interestingly, there are no conditions of participation for physicians or non-physician practitioners. A licensed physician or nurse practitioner who meets the relevant educational requirements completes the forms

for enrollment and becomes a Medicare participant. In the Medicare+Choice program there are defined quality mechanisms that plans must provide as part of their continuing compliance with their rules for participation.

Perhaps the most significant compliance-relevant quality regulation in the Social Security Act has been the PRO program where the operating entities are now referred to as Quality Improvement Organizations or QIOs. These physician-based organizations have the responsibility by statute to review the cost and quality of care rendered to Medicare patients to assure it was medically necessary, met professionally recognized standards of care, and in the case of inpatient care was provided in the most economical location to meet the patient's needs.

Originally enacted into law in 1982, following on the heels of the old PSRO program, the program has endured a checkered career in terms of both funding and focus. The initial emphasis was on whether hospitals would game the DRG reimbursement system. Over time the work plans moved to a far more quality-driven mechanism with almost academic study designs and reviews. Today, the program focuses on specified measures of quality and how to produce them. It targets nursing homes, HHAs, hospitals and physicians in its jurisdiction. For all of its quality improvement orientation, though, the program has always had the authority to recommend exclusions and fines where there are either substantial failures in a substantial number of cases to provide appropriate care or in any instance of a single gross and flagrant violation of professional standards.

The EMTALA statute and regulations (Emergency Medical Treatment and Active Labor Act) is also a quality-relevant compliance issue because of the requirement for appropriate medical screening, timely response in person by an on-call specialist and the interrelationship of these provisions with the demands of managed

care organizations. Here, again, liabilities run separately to both hospitals and physicians to meet the applicable obligations. Addressing these concerns in a compliance program would seem important since there are \$50,000 civil money penalties available for violations --- and they do get imposed. Moreover, the scope of EMTALA has expanded dramatically over the years so it is not merely applicable to the patient in the dedicated emergency department, but can take into account patients in transport, as well as patients in outpatient settings of a hospital, depending on how the facility is organized. Still further, some of the implications of EMTALA also relate to medical staff activities in terms of on call responsibilities (See AGG Note, Vol 15, No. 1, February 2003, "The Organized Medical Staff: Should Anyone Care Any More?")

Similar quality-relevant federal law is present in the Health Care Quality Improvement Act (HCQIA) which, like other peer review protection legislation at the state level, was intended to encourage more aggressive peer control of physician quality by protecting from liability, primarily in antitrust, hospitals, HMOs and physicians who take action to limit staff membership and/or clinical privileges of individual physicians when the action was taken in the good faith belief that it was in furtherance of quality and certain due process measures were provided. In addition, the hospital or HMO must report the action to the National Practitioner Data Bank. Failure to meet these standards results in loss of the antitrust exemption.

All of these major programmatic initiatives are known in health care delivery circles but frequently are ignored in compliance program development. Even lesser known are a number of specific exclusion and civil money penalty authorities that directly implicate quality.

Exclusions and CMPs related to Quality

A provider, whether a hospital, supplier or physician, can be excluded from the federal programs for providing items or services to patients (whether or not eligible for benefits under Medicare or Medicaid) which are substantially in excess of the patient's needs or of a quality which fails to meet professionally recognized standards of health care. (42 USC 1320a-7(b)(6)(B)). This catch all provision does not specify a body of standards to be referenced to make this judgment. Where a QIO has norms, criteria and standards on a point, they would certainly be relevant. After that, national clinical practice guidelines or even expert witness testimony might be looked at to make this kind of case.

Civil money penalties are the punishment of choice for a range of other problems. Where claims demonstrate a pattern of medical items or services that a person knows or should know are not medically necessary (42 USC 1320a-7a(a)(1)(E)), up to \$10,000 CMP is available to the government. Again, no standards are referenced.

A different type of problem is at issue where a civil money penalty of \$25,000 may be imposed on anyone who provides false or misleading information that could be expected to lead to premature discharge of a hospital inpatient (42 USC 1320a-7a(a)(3)). Here it should be noted that the complained of action does not have to actually produce harm. Whether a discharge is premature is a judgment assigned to QIOs, but there is no formal, external standard regarding the implications of the relevant inappropriate information. "Mr. Smith, you will have to leave the hospital tomorrow because Medicare won't pay for any more days on your admission" likely would qualify as misleading.

Finally, in a recognition of the changed financial environment for hospitals, physicians and managed care plans, two other aspects of the law address the potential for underuse in

settings where the incentives to hospitals and physicians are 'aligned'. A \$2,000 civil money penalty may be assessed in each instance where a hospital makes payments to physicians to reduce or limit services (42 USC 1320a-7-a(b)) even if they are reduced from a baseline of overuse! Here a penalty may be imposed on the hospital for making the payment and another penalty may be imposed on the physician for accepting it. This provision formed the basis for the OIG's rejection of most 'gainsharing' programs. Similarly in a provision which is applicable under the statute on a stand alone basis as well as under Stark (42 USC §1395nn(e)(3)(B)), penalties can be assessed for physician incentive plans that put physicians at substantial financial risk and do not adhere to the regulatory protections there which are primarily reporting to the government and disclosure to the beneficiaries. (42 CFR §417.479 and 42 CFR §1003.100 et. seq.)

Programmatic Integration

The scope of quality concerns which are tied to fraud and abuse penalties has expanded. New theories of liability are being hatched by eager prosecutors. Yet, compliance has remained an activity apart from the core mission of most healthcare organizations, even those which adopt compliance programs. Compliance is often conceived of exclusively as a billing-related function. Even in that regard, eager, often young, compliance officers, envision their roles more as "gotcha – this needs to be reported and repaid" than integral to the very purpose of the health care enterprise.

Whether as a physician practice, a hospital, a SNF, or even a managed care organization, some fraud and abuse penalties lurk on the quality horizon. To treat all of these activities – billing, aligning incentives, managing discharge planning, EMTALA liabilities and peer review, for example – as if they are unrelated to each other can only contribute to the pervasive sense of regulatory overload which afflicts most health care practitioners, providers and plans.

To apply techniques which anticipate all of these concerns, address them in an organized way without adding undue administrative burden, in a setting which furthers appropriate evidence-based care ought to be the shared goals of compliance and the basic health care mission. The true integration of compliance into the fundamental strategic plans of the organization would strengthen both activities. In fact, there is a way to do this.

A Unified Field Theory Applied

From documentation requirements to substantiate both the services rendered and their medical necessity, to quality assurance demands as part of conditions of participation, to the delegated authority assigned to medical staffs by hospital boards in implementing their fiduciary roles, to basic risk management and the impact of public reporting of performance, there are a myriad of disparate forces which can lead to managerial and operational paralysis if confronted as if they are disconnected. The impact of these forces makes it clear that a new approach needs to be considered.

Five core principles would advance these goals: (1) the more that physicians and health care delivery systems *standardize care* reflecting evidence based medicine in explicit ways, the more quality will be improved, misuse, underuse and overuse will diminish, thereby avoiding those compliance liabilities and time will be saved for all concerned – especially physicians. (2) Greater *simplification* throughout the system in terms of documentation, payment, incentives and delivery processes, would lower the risk of error in clinical terms, and make the delivery process more efficient while avoiding compliance problems. (3) To increase the *clinical relevance* of the control systems for compliance and otherwise, and especially with regard to payment and documentation, would be a major advance for compliance and quality. (4) To *engage the patient* actively in determining goals and expectations regarding care delivery

would lower malpractice risk, prevent complaints to the PRO/QIO or others with regulatory authority over quality, and would substantively create more patient-centered care. (5) Finally, to accept *accountability at the locus of control* would enhance the transparency of the system, as recommended in “Crossing the Quality Chasm”. This means physicians should be measured for what they can control, which is the application of appropriate science and the quality of their relationship with their patients – and systems of care should be responsible for work processes and outcomes.

The critical foundation for all of these principles is the wide and deep use of clinical practice guidelines (CPGs) throughout health care enterprises to order how care is delivered, documented and paid for.

The theory behind these ideas has been developed and expanded in a white paper, “Doing Well by Doing Good: Improving the Business Case for Quality” (http://www.uft-a.com/PDF/uft-a_White_Paper_060103.PDF) authored by Alice Gosfield and James Reinertsen, MD available at www.uft-a.com – a new website devoted to consideration of the many ways in which this unified approach to health care can improve quality, save time, and add efficiency. By implication it would also improve compliance.

To reorient compliance away from administrative minutiae, and toward basic themes of health care delivery – of which quality care is the most significant – would improve both compliance and quality. To make compliance programs more seamless components in health care and avoid the “gotcha” syndrome which makes the folks from whom compliance is sought dread the vision of the compliance officer’s arrival in their office, it is important to shift the view and role of compliance. The dual goals of improved quality and compliance are not only complementary, they can reinforce each other. Some practical steps are worth considering:

1. Review the enforcement challenges identified here – EMTALA, conditions of participation, PRO/QIO measures, premature discharge, etc. – and incorporate them explicitly in your compliance program.
2. Read “Doing Well By Doing Good” and the related publications available at www.uft-a.com which deal with how broader applications of CPGs make a real business case for quality.
3. Make use of the provision in the Stark final regulations (42 CFR 411.357(o)) which permits a hospital to provide to its staff physicians, *at its expense*, compliance training. To focus on the compliance/quality nexus in a consistent manner, both in the hospital and the physician office, means the hospital can legitimately help physicians to help themselves in ways that will have real meaning for their time spent with patients, their bottom lines and their own compliance concerns.
4. Develop meaningful techniques to assure services are “medically necessary.” Since none of the fraud and abuse statutes references any standards against which performance will be measured, to base care delivery, documentation and billing explicitly on national CPGs not only solves that problem, but improves quality at the same time.

Conclusion

The rise of quality as a fraud and abuse issue can no longer be ignored as a fundamental compliance challenge. There is a far better way to look at this issue, however, than merely from the perspective of prosecutorial and enforcement scare tactics. To connect compliance with the fundamental care delivery process in a way which enhances clinical performance while it lowers false claims risk and *saves time* while improving efficiency, would seem so seductive as to command attention throughout the health care system.

This approach should appeal to physician practices, hospitals, integrated systems, SNFs and plans. Most providers today – and especially physicians – are staggering under the weight of decreased reimbursement, increased expenses, and a crushing administrative burden. Most also view compliance as a particularly odious and onerous undertaking that adds to their load without any real value. It is time to change that view. The quality/compliance nexus offers a real opportunity to reorient those functions with others to fundamentally improve the provider-clinician work environment while truly improving health care quality. Wake up to the possibilities!

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