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Regulatory compliance issues in physician compensation arrangements

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Hospitals and health care systems are increasingly using physician practice acquisitions and employment relationships as a primary physician alignment strategy. In contrast to the physician employment wave that took place in the 1990s, however, hospitals and health care systems appear to be targeting specialists for employment. Specialty physician groups often compensate their member physicians under very unique and complex compensation plans. These specialists frequently demand that the hospital system create unique compensation methodologies which meet the objectives of the newly-employed physicians. The purpose of this article is to identify key issues and concepts that a hospital system must keep in mind in order to structure physician compensation arrangements that remain compliant with the federal Stark law.

Legal and compliance issues in physician compensation

A critical question in any physician employment model is: How will the physicians be paid? A variety of considerations come into play in determining whether the system will utilize a direct employment model, or whether it will create a physician organization which meets the "group practice" definition under Stark, with the physicians providing services as members of or physicians in the group practice. The proposed compensation method will have a significant impact on the system's choice of employment model. In fact, it is not always clear if the employment model drives the structure of the compensation model; or, if promises made to the physicians during the compensation negotiations will drive the structure of the employment model.

Choosing the compensation model

As mentioned above, there are a variety of factors that come into play in deciding which physician employment model is the best "fit" for the hospital system and the physicians. Whether the hospital is for-profit or tax-exempt, the size and nature of the group of physicians to be employed, whether the hospital is located in a strong "corporate practice of medicine" state, and other factors will affect that decision. Physicians' expectations and desires regarding their compensation will also be a significant factor, if not the most significant factor, in dictating the preferred physician employment model.

Any type of employment arrangement with a referring physician will create a "financial relationship" between the hospital system and the physician. The employment relationship will therefore implicate the Stark law. The hospital system must structure the relationship with the physicians as either (1) an employment relationship which meets all of the criteria of the "bona fide employment relationships" exception, and pay compensation in a manner that meets all of the criteria applicable to compensation under that exception; or, (2) the system must create a "physician organization" that meets all of the criteria of the "group practice" definition under the Stark law, including the criteria that address the payment of compensation to physicians in the group practice.

In Phase I of the Stark II Regulations released in 2001, the Centers for Medicare and Medicaid Services (CMS) set out "general principles" that "govern the application of the statute to the manner in which physicians are paid." Among the "general principles" listed by CMS were:

1. A "referral" does not include "designated health services" (DHS) under the Stark law that are personally performed by the physician.
2. With regard to group practices, the law protects "bona fide group practices," and not "loose confederations of physicians who come together as a 'group' substantially in order to capture profits of DHS" under the in-office ancillary services exception.
3. The physician compensation provisions for group practices under Stark affect only the distribution of revenues derived from DHS.
4. Physicians may be paid in a manner that directly correlates to their own personal labor.
   - "Productivity" refers to the "quantity and intensity" of the physician's own work.
   - "Incident to" services may be included in a physician's productivity only if the physician is a "member" of a bona fide group practice and the physician personally performed an initial service related to the "incident to" service and remains actively involved in the course of treatment. Physicians would not receive credit toward productivity if they are only assigned to supervise the "incident to" services and bill for them.
5. Members of a group practice may receive shares of the "overall profits" of the group, which may include revenue derived from DHS, so long as those shares do not directly correlate to or reflect the volume or value of referrals for DHS performed by someone else in the group.[1]

In Phase II and Phase III of the Stark regulations, CMS re-emphasized the "flexibility" afforded to group practices in compensating physicians in the group. In the Phase II regulations, CMS stated that the

> "...statute permits a group practice to divide revenues among physicians in ways that are very different from the ways other DHS entities are permitted to share revenues with employed or independent contractor physicians. The statute recognizes the difference between physicians in a group dividing income derived from their own joint practice, and a hospital (or other entity) paying a physician employee or contractor who generates substantial income for the facility that would not ordinarily be available to a physician group."[2]

In the Phase III regulations, CMS simply stated that the "Act allows group practices more flexibility in compensating physicians . . ."[3] Thus, CMS has made it clear that the Stark law, by statute, affords group practices a much greater degree of flexibility in structuring compensation relationships with physicians in the "group."

Compensation under an employment model

If a hospital system decides to utilize a "pure employment" model for employing its physicians, the employment relationship must meet all of the criteria of the "bona fide employment relationships" exception under Stark.[4] With respect to compensation, the criteria of that exception are as follows:

- The amount of the "remuneration" under the employment is (1) consistent with the fair market value of the services, and (2) except with regard to productivity bonuses, is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician.
- The remuneration is provided under an agreement that would be "commercially reasonable" even if no referrals were made to the employer.
- The compensation formula may provide for the payment of a "productivity bonus," provided that the "productivity bonus" is based solely on services performed personally by the physician.

CMS has provided very little commentary or guidance with regard to the "fair market value" and the "commercial reasonableness" criteria of this exception. As a matter of practice, hospital systems have relied on fair market value appraisals prepared by appraisers with substantial experience in valuing physician compensation arrangements. The valuation expert will typically develop a range of fair market value compensation, based on the specialty of the physician, using a variety of available physician compensation surveys. The hospital system will then structure a compensation arrangement under which compensation paid to the physician will fall

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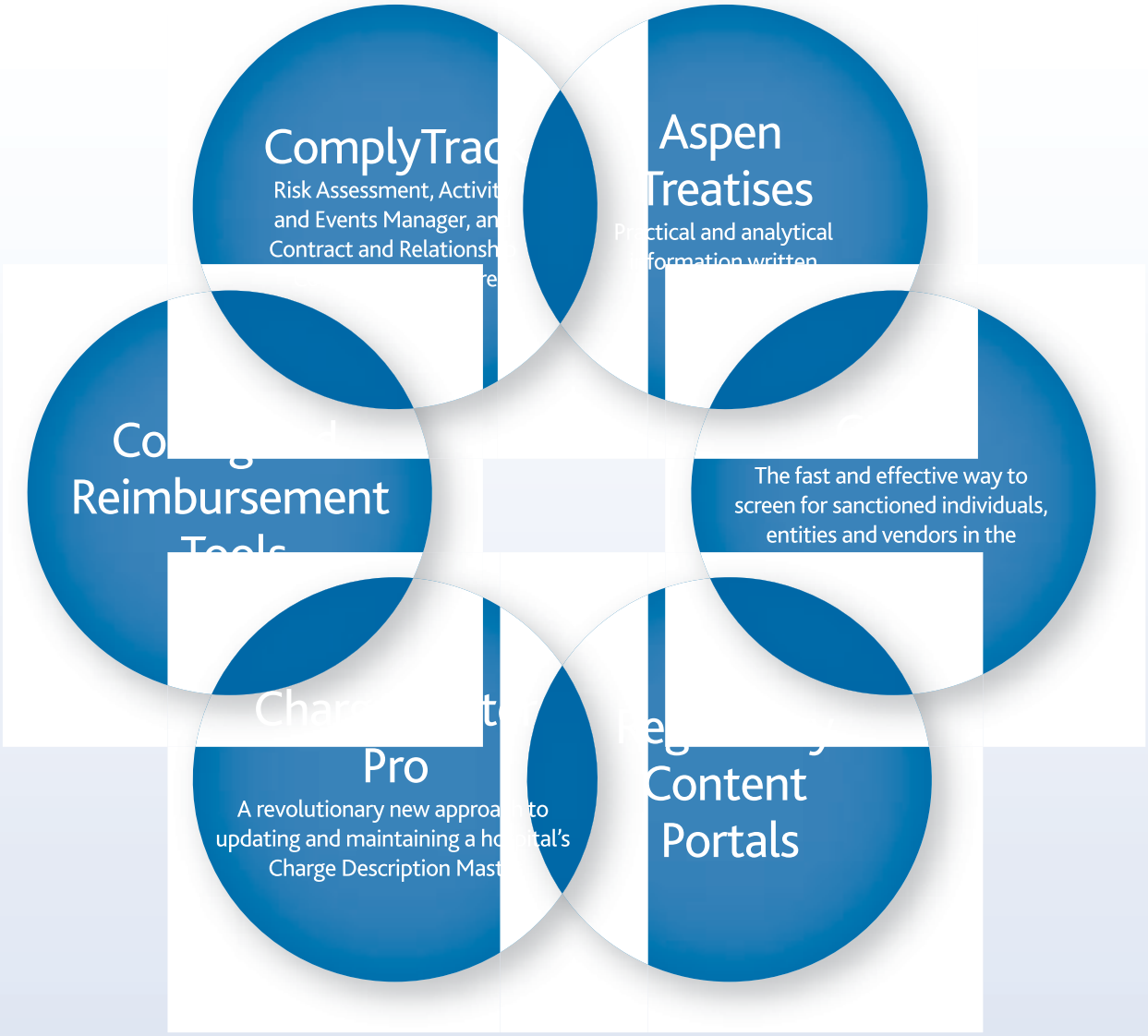

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within the fair market value range.

If the compensation arrangement consists of a base salary, with perhaps an opportunity for a fixed or objectively determinable bonus, then the analysis is relatively straightforward. If, however, the compensation is based, in whole or in part, on a productivity formula, then the analysis becomes a bit more complicated. In such a case, the appraiser may perform an analysis using projections of possible compensation paid under the proposed productivity formula; the projections are based on historical performance of the physician and assumptions of different levels of performance in the future. The appraiser will then determine if the compensation that may be paid under the formula, assuming various levels of productivity, will remain within a fair market value range. In arrangements where compensation is based, in whole or in part, on a productivity formula, it may be advisable to incorporate a "hard cap" on compensation paid under the agreement, or at least an "out" for the system in the event compensation exceeds fair market value, to ensure that compensation at all times remains within a fair market value range and the arrangement otherwise complies with the Stark exception.

In addition to the requirement that the amount of compensation paid under the employment must be consistent with the fair market value of the services, keep in mind that the "bona fide employment relationship" exception also includes a separate requirement that the remuneration must remain "commercially reasonable, even if no referrals were made to the employer." This "commercial reasonableness" requirement is a separate requirement from the fair market value compensation requirement, and is often overlooked in analyzing proposed compensation arrangements for compliance with the Stark exception. CMS has provided virtually no guidance to the industry as to how this criterion should be applied in practice.

The "commercial reasonableness" requirement is a more subjective criterion. The key question in analyzing compliance with this criterion is to determine whether it appears that the physician's compensation may exceed that which is "reasonable;" (i.e., whether the compensation exceeds that which a prudent business person would pay the physician, given the nature and type of work performed by the physician and the productivity of that physician). If it appears that the physician is being overcompensated given his or her effort and productivity, then the implication is that the physician is being compensated based on "other" revenue that he/she generates for the hospital. This, of course, would raise significant issues under the Stark law.

One way of analyzing compliance with this requirement could be deemed the "physician practice management company (PPMC) test." Under this test, the hospital system would assume the role of a PPMC that had purchased the assets of the practice and, directly or indirectly, employed the physicians. Under this model, of course, physicians were not in a position to, and in fact did not, refer patients to the PPMC for services. Therefore, the analysis of the "reasonableness" of the compensation to be paid to the physician was based solely and strictly on the physician's personal professional services, and on the "value" that he or she added to the physician organization by virtue of the performance of professional medical services.

Finally, a note about "personal productivity bonuses" that may be paid consistent with the "bona fide employment relationships" exception. This exception permits the payment of "productivity bonuses" to employed physicians provided that the bonuses are based strictly on services that are personally performed by the physicians. Therefore, the physician may not receive "credit" for "incident to" services (unless he/she performed the initial service and remains actively involved in the treatment), or for any other services that are not personally performed by the physician. The physician may receive "credit," however, for labor in the provision of DHS, so long as the physician has personally performed the DHS.

Group practice model

As we mentioned above, CMS has clearly and consistently stated that a physician organization that meets the definition of a "group practice" under Stark possesses much more flexibility in structuring compensation arrangements with physicians in the group. The statute and the regulations are clear that the group may distribute "profits" of the group to its member physicians, provided that:

- The method or formula of distribution is determined before the receipt of payment for services that give rise to the overhead expense or production of income (i.e., the compensation formula must be set in advance, before any revenue is collected or before the start of the fiscal year), and
- The manner of calculating the shares of the overall profits to be distributed to members of the group is not determined in any manner that directly relates to the volume or value of referrals of DHS by the physician.

CMS has also made it clear that the group may also pay physicians in the group compensation which includes a "productivity bonus"; and, that the productivity bonus may be based on services personally performed by the physician, as well as "incident to" services, as long as the physician personally performed the initial service related to the "incident to" and remains active in the patient's treatment.

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Thus, CMS has plainly stated that a group practice may distribute "profits" of the group to its member physicians, so long as the distribution methodology does not directly correlate to or reflect the volume or value of referrals of DHS by the physicians within the group. CMS has given several examples of distribution methodologies which it believes are permissible "indirect" means of distributing profits of the group, including:

- A per capita distribution of overall profits
- The distribution of DHS revenues pursuant to a formula that reflects the distribution of revenues attributable to services that are not DHS (such as professional services); or
- If the DHS revenues of the group are less than 5% of the overall revenues of the group, then any methodology is permissible, so long as no single physician in the group derives more than 5% of his or her overall compensation from distributions of DHS revenue.[5]

CMS emphasized that the above methods provide "absolute assurance" that distributions are not directly related to referrals, but that the list is not exhaustive, and that groups are free to devise other formulas so long as they are "reasonable, objectively verifiable, and indirectly related to referrals."[6]

CMS also stated that distributions of profits may be made among the physicians in the group, as a whole, or in any "component" of the group practice which consists of at least five physicians. In the Phase II Commentary to the Stark Regulations, CMS confirmed that any component or subdivision of the group was permissible, so long as it consisted of at least five physicians.

Conclusion

There are advantages and disadvantages to utilizing either the employment model or the group practice model with respect to the structure of physician compensation arrangements.

Under the employment model:

- The hospital system will not need to create and maintain a physician organization that meets the definition of a "group practice" under Stark.
- The limitations on compensation under the criteria of the "bona fide employment relationships" exception will necessarily limit the range of compensation models, which would generally result in simpler compensation plans that are easier to administer.
- Despite these limitations, however, the opportunity to include a productivity-based component to the compensation model, based on the physician's personally performed services, should allow the system to build "incentives" into the compensation model to encourage hard work and productivity.

From a regulatory compliance standpoint, however, the health care system must be mindful that compensation to be paid to the employed physicians must at all times remain within the range of fair market value compensation for the physician, as determined by a fair market value appraisal. In addition, the system must constantly evaluate the compensation methodology, and the compensation actually paid to the physicians under the formula, to ensure that the compensation is "commercially reasonable," even if the physicians were making no referrals to the system's hospitals and other health care facilities.

Under a group practice model:

- The system will have considerably more flexibility in structuring physician compensation formulas.
- The system may "pool" funds generated by physicians working within the "group" and may distribute those revenues based on a variety of formulas, provided that the formula does not directly correlate to or reflect the volume or value of referrals by the physicians in the group of patients for DHS.

CMS has provided examples of acceptable distribution methods, but has made it clear that the list is not exhaustive, and that systems are free to devise other types of methods, so long as the method does not directly relate to or reflect the volume or value of referrals. In addition, CMS has afforded hospital systems the flexibility to create "components" within the group practice, perhaps based on specialty or office location, and applying the formula to a "component" of the practice for compensation purposes, so long as the "component" consists of at least five physicians.

In order to avail itself of the flexibility afforded within a group practice model, however, the health care system must form a physician organization, and that physician organization must at all times meet all of the criteria of the definition of a "group practice" under the Stark law. If at any time the physician organization does not meet the definition of a "group practice," then the compensation arrangements between the group practice and the physicians would immediately fall out of compliance with the Stark law. In addition, to the extent that the group practice is providing DHS as in-office ancillary services of the group and revenue generated from this DHS is included in the "pool" of revenue that is distributed to the physicians, then the group must also meet all of the criteria of the "in-office ancillary services" exception under the Stark law.

In short, the flexibility afforded to a hospital system in structuring compensation arrangements with employed physicians under a group practice model comes with a price—a significantly higher regulatory compliance burden. ■

1 Stark Phase I Regulations, 66 Fed. Reg. pp. 875-876.
2 Stark Phase II Regulations, 69 Fed. Reg. p. 16066.
3 Stark Phase III Regulations, 72 Fed. Reg. pp. 51021-51022.
4 42 CFR § 411.357(c).
5 42 CFR § 411.352(i)(2).
6 "Phase I" Regulations, 66 Fed. Reg. pp. 909-910.

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EMTALA today as a high-risk compliance area

By Joanna Conder, MPP

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The Emergency Medical Treatment and Active Labor Act (EMTALA) has always been considered a high risk area by the Department of Health and Human Services (DHHS) Office of Inspector General (OIG) that should be subject to ongoing auditing and monitoring. The Centers for Medicare and Medicaid Services (CMS) has also expressed great concern about this risk area. However, regulatory and legal EMTALA enforcement actions have been limited. This may soon be coming to an end. OIG is increasing its enforcement focus on EMTALA and CMS is clarifying areas of the law that have been causing confusion. EMTALA is back on the government's radar. This renewed interest in the subject warrants hospitals and compliance officers to revisit their policies and procedures related to EMTALA.

Background

EMTALA was enacted in 1986 and has been popularly known as the patient antidumping statute. Its stated purpose is to ensure emergency care is available to everyone, without regard to a person's ability to pay.[1] It imposes a legal obligation on hospitals that participate in Medicare and operate an Emergency department (ED) to provide appropriate medical screening and stabilization care to persons who present themselves to the ED, before transferring them to another hospital or sending them back home. Violations of EMTALA may result in monetary penalties of not more than $50,000 (or not more than $25,000 in the case of a hospital with less than 100 beds) for each violation.

EMTALA has been lacking proper enforcement, in part as a result of poor data collection of EMTALA cases.[2] The DHHS does not maintain a centralized, updated database of EMTALA complaints or violations. One study estimated that 250,000 acts of patient dumping occur annually.[3] However, government enforcement efforts only detected patient dumping, on average, in approximately 0.01% of transfers.[4] Furthermore, poor enforcement has been reflected by the limited number of EMTALA court cases. In addition, case law shows the lack of uniformity among the courts interpreting EMTALA. These inconsistent court opinions limit the statute's effectiveness. Finally, CMS has taken direct termination actions against only few hospitals.

New compliance environment

All of this suggests a renewed interest in EMTALA. OIG has included a review of EMTALA compliance in its 2009 Work Plan. They plan to review CMS oversight of hospital compliance with EMTALA and identify regional variations of EMTALA complaints and cases referred to states. The review will focus on CMS systems of tracking complaints and determine whether peer reviews had been conducted before CMS decided to terminate providers who violated EMTALA. OIG reviews will definitely heighten CMS' interest in the subject and may lead to increased enforcement activities.

Furthermore, a growing number of experts are calling to shift the burden of proof for violations from the government to hospitals.[5] Under this approach, once a patient establishes a case that EMTALA requirements were violated, the hospital would have to prove that it is otherwise. If courts were to rule under this approach, it would likely increase enforcement of EMTALA.

While all this is occurring, CMS has recognized that some EMTALA requirements may be causing an unnecessary burden on certain hospitals. The Inpatient Prospective Payment System (IPPS) final rule was published in the Federal Register in August 2008 and applies to discharges on or after October 1, 2008.[6] The rule updates Medicare payments for fiscal year (FY) 2009 and provides regulatory guidelines for inpatient hospitals. Two important policy changes in the IPPS final rule may affect hospitals' operations and their compliance activities as related to hospital emergency services.

EMTALA requirements regarding hospital inpatients

In the 2003 stand-alone final rule on EMTALA, CMS determined that a hospital's obligation under EMTALA ends when that hospital, in good faith, admits an individual with an unstable emergency medical condition.[7] This provision clearly narrowed a hospital's duties under EMTALA, but did not address the question whether inpatient admission at one hospital ends EMTALA obligations for another hospital when an unstabilized patient is transferred. In the IPPS proposed rule, CMS suggests that EMTALA should apply to a hospital when an inpatient in need of specialized care (who presented to the admitting hospital under EMTALA) is being transferred to stabilize

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an emergency condition. This received many negative comments from the industry, for example:

- A change in policy is unnecessary as it is unlikely for a hospital to knowingly admit an individual with an unstabilized condition while it does not have capabilities to stabilize the condition.
- Hospitals with specialized capabilities will see an increase in the number of transfers, because the policy would encourage other hospitals to dump patients on them.
- The policy would have negative impact on patient care. For example, a hospital may decide to transfer a patient whose condition deteriorated following admission.

In response to these concerns, CMS clarified the language in the IPPS final rule to say that

> "… once an individual is admitted in good faith by the admitting hospital, the admitting hospital has satisfied its EMTALA obligation with respect to that individual even if the individual remains un-stabilized and a hospital with specialized capabilities does not have an EMTALA obligation to accept an appropriate transfer of that individual."

During the commentary period to the proposed rule, hospitals with specialized capabilities were concerned that they might be overburdened with the number of transfers they would receive. The IPPS final rule seems to mitigate these concerns to some extent. Nevertheless, there is a possibility that now, while seeking emergency care, more patients will go straight to tertiary hospitals, such as large medical centers, knowing that another hospital that lacks the necessary capabilities may admit them, not be able to stabilize them, and then eventually transfer them to a specialized hospital.

Physician on-call requirements

EMTALA requires hospitals to keep a list of physicians who are on call to provide stabilizing treatment. If a physician on the list is called by a hospital and either fails to or refuses to appear within a reasonable period of time, EMTALA may be violated. CMS has recognized that many hospitals struggle to provide specialized on-call coverage, due to physician shortages. The IPPS final rule provides hospitals with a more flexible way to comply with the on-call list requirement. Hospitals can now decide to participate in community/regional on-call plans and designate a specific hospital in a region as the on-call facility for a specific time period and/or for a specific service. If an individual arrives at a hospital other than the designated on-call facility and the individual cannot be stabilized by the hospital's ER staff and requires the services of an on-call specialist, the individual may be transferred to the designated on-call facility. Importantly, a hospital that is not designated as an on-call facility on a particular day still has obligations under EMTALA to provide appropriate medical screening and stabilization care before transferring the patient to another hospital.

To ensure compliance, participating hospitals must include the following elements in the community on-call plan:

- Clear description of on-call coverage responsibilities for each hospital;
- Definition of the specific geographic area to which the plan applies;
- Signatures of an appropriate representatives of each hospital participating in the plan;
- Assurance that any local and regional emergency medical service (EMS) system protocol includes information on community on-call arrangements;
- Statement specifying that even if an individual arrives at a hospital that is not designated as the on-call hospital, that hospital still has an EMTALA obligation to provide a medical screening and stabilizing treatment within its capabilities;
- Statement specifying that all participating hospitals must operate according to the EMTALA regulations governing transfers; and
- Annual reassessment of the community on-call plan by the participating hospitals.

Recommendations

Following are a number of actions that hospitals and compliance officers should be taking in response to this changing EMTALA compliance environment.

1. Hospitals participating in the community on-call plan should ensure they have written policies and procedures that address various on-call situations, such as when on-call physicians are unable to respond to the call due to situations beyond their control or when they have simultaneous on-call duties.
2. The community on-call arrangement may disproportionately designate most of the specialized on-call services to one facility. Therefore, while entering into on-call arrangements, hospitals with specialized capabilities need to carefully assess how many specialty on-call services they will be able to provide to other participating hospitals. Specifically, they need to analyze how additional transfers will affect their day-to-day operations in terms of physical space, medical and non-medical resources, costs, and revenue cycle.
3. Hospitals should consistently apply the same facility standards to individuals who arrive at the ED.
4. Hospitals that operate an ED should ensure that an individual who arrives at the ED is appropriately evaluated and if it does not have the capability to provide appropriate care, the hospital should

transfer, rather than admit, the individual. This assessment may be difficult for hospitals with insufficient or inadequate resources.

5. Hospitals should have policies and procedures in place to ensure that a person with an unstabilized condition is not knowingly admitted to the hospital.
6. Hospitals need to ensure that their staff has extensive knowledge of and training on the EMTALA requirements.

Conclusion

With the renewed government interest in EMTALA, hospitals should ensure that they have an effective compliance system that can track and evaluate any potential violations of the EMTALA regulations. Further, compliance officers should consider increasing the priority for ongoing auditing and monitoring of EMTALA issues.

1 42 U.S.C. §1395dd. Congress enacted EMTALA under section 9121 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Public Law No. 99-272, 100 Stat. 164-167, available at: http://www.medlaw.com/statute.htm
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3 Id., p. 195
4 Id., p. 199
5 Dana E. Schaffner, EMTALA: All Bark and No Bite, University of Illinois Law Review, Vol. 2005, No. 4, p. 1040
6 Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009, 73 Fed. Reg. 161, 48434-49084 (Aug. 19, 2008)
7 Medicare-participating hospitals treating individuals with emergency medical conditions, 68 Fed. Reg. 174, 53221, 53243 (Sept.9, 2003)

New procedure for the CEU Quiz

The CEU quiz will no longer be mailed to you in the envelope with each issue of Compliance Today. To take the quiz, please go to **www. hcca-info.org/quiz** and print a copy. You will still need to mail or FAX the quiz to Liz Hergert to obtain credit. You will still have one year after the publication date to submit each quiz. An archive of current quizzes is available online. We are planning to put the quiz online in the future, so you will be able to take the quiz online to get your results and credits faster.

feature article

Meet D. Ryan Whitehill, CHC

Manager, Ethics & Compliance Training, Ethics & Compliance Department at Tenet Healthcare Corporation

Editor's note: This interview with D. Ryan Whitehill was conducted in late November 2008 by Shawn DeGroot, a member of the HCCA Board of Directors. Shawn may be reached by e-mail at sdegroot1@rcrh.org.

Ryan Whitehill may be reached by e-mail at ryan.whitehill@tenethealth.com.

SD: Please tell our readers about your background.

RW: I initially got into the training and education field a little over 10 years ago with a large telecommunications company in Missouri. I was a technical trainer who taught customer service and sales representatives. It was high volume, high energy, and a great way to learn about organizational structure, implementation, and to shape my presentation style. After several years of traveling and moving with the company, I moved into health care after being recruited by a large health insurance company in Houston, Texas. A lot of high energy, fresh ideas, and some great implementation results led me from Houston to Ft. Lauderdale, Florida, where I continued my work in health insurance. I joined Tenet Healthcare in Dallas, Texas four years ago as Manager of the Ethics and Compliance Training program.

SD: Tell us about ethics and compliance training with Tenet Healthcare.

RW: Being such a large organization, training with Tenet is big business. In the second year of our Corporate Integrity Agreement (CIA), we trained 87,815 employees and contractors, provided just under 325,000 hours of CIA-required training, and achieved an overall completion rate of 99.92%. Our team and our structure are what make this possible.

SD: Tell me more about your compliance structure.

RW: Whether the topic is training or overseeing quality of care and billing compliance issues, we are poised for action and results. Overall, we have 76 members in our department who are solely devoted to ethics and compliance at Tenet. Fifty-one of those members are onsite hospital compliance officers (HCOs) who are responsible for implementing policies and procedures and managing the compliance programs in their respective hospitals. Our entire structure reports directly to Audrey Andrews, our Chief Compliance Officer, who reports to the Quality, Compliance and Ethics Committee of the Tenet Healthcare Board of Directors. This structure ensures our true independence.

SD: What types of training do you provide?

RW: General ethics and compliance training, billing and reimbursement training, coding training, cost report training, clinical quality training, focus arrangements training, and privacy and security training are main

areas of focus that we provide annually, but we also stay on top of any new regulatory changes like the Deficit Reduction Act and California's SB 541 and AB 211.

SD: Is the Tenet Healthcare compliance training program comprised of live and computer-based training?

RW: The vast majority of our training is provided live by members of our team, but we also use computer-based training for more specialized topics. Live training is the only way to go if you really want to effectively sell your program, implement concepts, change culture, and have an overall effective compliance program. We find that it's more meaningful, better received, and you get way more bang for your buck.

SD: How do you implement and deliver such a large program?

RW: The first step is to know the scope of the project. Because our Corporate Integrity Agreement encompasses such a large number of people (63,000 employees, 20,000 contractors, 24,000 physicians), we have to use technology to its fullest. The great thing is that, with a little out-of-the-box thinking, we are able to use our current human resources/payroll, contractor management, and learning management systems to accomplish this task. By making a few changes to our current systems, we were able to code more than 80,000 covered persons by their job duties for both live and computer-based training assignments. This gives us a GPS-like ability to track an individual person and our overall progress at any given time.

The second step is to partner with our corporate, regional, and hospital-based compliance committees, human resources teams, clinical education teams, and operations teams to keep everyone informed and create a schedule of events that doesn't impact the quality of care or routine operations our hospitals provide while we are achieving our annual training goals.

The third step is to "go for the gold" and make our program meaningful. We customize our different programs by understanding who and what level of person is in the audience and what it takes for a person to grasp a concept. We use lots of audience interaction, both video and streaming video, stay on top of pop culture, and use some edgy, attention-getting material to drive our points home. In the second year of our CIA, we provided more than 3,350 hours of Continuing Medical Education credit to our excepted physicians for compliance training. We've even started testing the ability of our users to download some of our training videos to their iPods. In today's age of marketing bliss, your program has to be as stimulating and attention-getting as the main stream media. When a nurse walks out of one of our sessions and says, "That was the coolest compliance training I've ever seen," I know we've done a good job.

SD: Conceptually, was the program self-developed or was a consultant hired to develop the program?

RW: The great thing about Tenet is that we have the ability, the talent, the resources, and the people to develop our own program. We're not only constantly cascading information and ideas both up and down through our department, but with other departments within the organization. We heavily rely on the information provided to us by our independent review organizations to develop our work plans and also connect with our peers in other organizations to keep on top of our game. It's exciting to see how our entire organization has evolved over the past four years, and it's a thrill to be a part of it.

SD: How do you obtain "buy-in" for participation in your training program?

RW: We're not only working to meet the obligations of our CIA and restore the trust of federal health care programs, but we're creating a culture of compliance at Tenet. We feel that the primary way to obtain buy-in is to ensure that our content is fresh and relevant to our employees. We also have great support from our senior leadership, including our CEO and the Tenet board of directors, all of whom lead the way in participating in training. In addition, we make it clear that training is not an option. We suspend and terminate anyone who does not meet required training obligations. It's just that simple.

SD: Tell me about Tenet's "Compliance U." Was it reviewed and approved by the board of directors?

RW: Our HCO position is an extremely challenging position in the hospital. As

members of our team, our 51 HCOs have multiple roles to play, responsibilities to oversee, and duties to complete. As you can imagine, there is a lot to learn, so we developed Tenet's "Ethics & Compliance University" or "Compliance U" for our new and existing HCOs. In essence, it's a roadmap for success. For our new HCOs, it's a formalized orientation where, over the course of several months, they complete a series of self-study tasks as well as work with their regional compliance directors, peers in the field, and members of our Corporate Ethics & Compliance team to quickly get up to speed. For our existing HCOs, it's a series of educational tools to ensure our team has the knowledge and tools they need to succeed, as well as ensuring our work is consistent throughout the organization. Our chief compliance officer reviewed Compliance U with the Quality, Compliance and Ethics Committee of our board, and they fully support it. We have an exceptional board that is very focused on ensuring that we have an effective compliance program.

SD: So what's next?

RW: (Laughs) All I can say is that it's been a great ride thus far, and it only gets better from here! ■

Hope for Compliance? The personal dynamics of compliance work

By Michael Paul, CGFM, CHC

Editor's note: Michael Paul is the Senior Manager of Payor Compliance for the Public Provider Reimbursement Unit of the University of Massachusetts Medical School division, Commonwealth Medicine in Worcester. The Public Provider Reimbursement Unit does medical billing and reimbursement management for public health and human services facilities and programs in Massachusetts. He may be reached at michael.paul@umassmed.edu.

Compliance managers all face various challenges in their daily jobs, from maintaining a compliance program, to impressing upon people the need for an ethical culture, to keeping up with the latest regulations. But, one of the hardest things of all is helping people to have enthusiasm for compliance. In many jobs, the only person who needs enthusiasm is the one doing the job; in compliance, the whole organization really needs to buy into compliance, and if they can do it with enthusiasm, success is much more likely. In a lot of organizations, however, the attitude of most people is anything but enthusiastic. Some will humor the compliance manager and go along with the training and procedures, as long as they are frequently reminded. If we are lucky, compliance managers will get most of the people "on board" enough to accept compliance as a necessary thing to avoid penalties in an age fraught with complicated legal risks, because they understand that to protect the healthcare organization's governmental revenues and guard against penalties, a culture of compliance is necessary to survival. But enthusiasm?

The great culture-divide

Often the difficulties in managing a compliance effort stem from a culture-divide that exists between managers and their staff. As much as we like to think that our ideas as managers and directors are embraced by the whole organization, there is more often than not a difference in perspective that depends on job status. I call it the "front room-back room phenomenon." Managers develop policies and present them to workers. The managers talk the talk, workers nod their heads and smile agreeably. Afterwards, the managers all feel self-assured and say how well they thought the meeting went. The workers meanwhile, when they are alone and back at their stations, slide right back into doing things they way they always did, perhaps complaining about their jobs, and usually saying that management has no clue about how things really work. Little communication has taken place and things don't really change.

I think this lack of connection derives from a fundamental difference in what makes executives who they are, and what makes workers, workers. Executives often get in the positions they hold by sacrificing personal time to study and attain advanced degrees and by working long hours. Their life-priority (at least judging by the way they spend their time) is work and success. Workers, on the other hand, work because they have to in order to live, and to a certain degree, merely tolerate their jobs rather than relish them. Their priority is not work, it is the rest of their life—family, friends, sports, hobbies, etc. They do their jobs, and often do a good job at them, but when the clock says it's time to go home, they have no hesitation whatsoever about leaving. At the risk of generalizing, I would say that people are more important to the average worker than money, careers, and success.

Although these patterns do not universally apply, they are prevalent enough that it creates a gulf between management and workers. Thus executives view workers as having values that are not beneficial to the organization, and therefore need to be guarded against and controlled and managed. Workers view execs as humorless, money-grubbing, self-absorbed individuals who don't have the best interest of the workers at heart. This creates a huge cultural difference between the two groups, which is the stuff of movies, comic strips, sit-coms, and water-cooler jokes everywhere. But this is not really the topic of this article; rather, it is meant to describe the backdrop of the set in which the work of compliance is played out. The real question comes out of this backdrop, and that is: How can people, both workers and executives, have a higher vision of their work so they can be motivated to embrace the ethics that the compliance officer is trying to instill in both? The answer, I believe, lies in the dynamics of hope.

The compliance challenges faced by workers

Why is hope important? Let's look at the area of medical billing and reimbursement as an example. Between all the various insurance plans and contracts, both private and governmental, there are more rules that describe what is covered, what is not, and how to bill for it than the IRS tax office ever dreamed of having. I try to explain this to non-billers this way: When you buy a $50 pair of shoes from a catalogue, you get a bill for $50 and you pay the company $50. When you buy $50 of medical services, your insurance company gets a bill for $385, the insurance pays $25, your wife's insurance gets a bill for $210 and pays $15, and you get a bill that you pay for $10, for a total of $50. The patient in the next examining room who got the same services may pay —after all the insurance payments and his own are totaled—$60, $45 or some other amount. The billers who work in the back room at the health center have the mind-boggling job of trying to keep all this straight.

Meanwhile, the rules keep changing. Every month I get dozens of e-mails from Medicare and Medicaid with changes to coverage, changes to cost-reporting rules, changes to billing protocols, and changes to computer systems that handle all this stuff. The billing people have to keep up with all these changes. To help them keep on top of all this, computer software companies have to regularly update their medical billing modules, test them, and release them. IT staff at healthcare providers must then install the upgrades, retest them, and then train billing staff in the changes. And of course, not everything in software always works the way it is supposed to, and the billing staff have to catch and fix the errors that often occur before the bills go out.

As good a job as they do, most of the time some of the bills will still go out with uncaught errors and get denied. These denials have to be researched, fixed, resubmitted, and sometimes are denied a second or third time before they finally get paid. Often there is incomplete information—out of date insurance cards, a missing code here or there, a wrong date of birth—that has to be corrected as well. Insurers have claim filing deadlines, and so sometimes it may just be too late and the money is lost altogether. In order to get the full $50 for a $50 service, clinical, admissions and billing staff have to do everything right and do it like clockwork every time.

People working in this environment may unfortunately have a discouraged attitude at times, and might even eventually compromise their ideals of doing everything perfectly. Instead, they just do what they have to, to get through the day until quitting time, hoping they didn't lose too much money for their healthcare provider.

It is into this environment that the compliance officer comes with his/her shiny shoes and pressed suit, offering "compliance training" to teach these non-compliant billers a thing or two. Front-room/back-room syndrome is about to strike. The culture divide in the room is like a gaping chasm waiting to swallow, digest, and spit out our compliance officer, without his/her even knowing anything has happened.

Is there any hope?

Before giving training to billers on how they should do their work more carefully, or how to be more attentive to rules, we first need to give them hope that there can be a better way to make a living. Of course, the compliance officer needs to do a cultural assessment to see whether the situation I have described exists, and not assume everything is as bad as I have described in my hypothetical billing department. If through the cultural assessment, however, we find out that these people are already trying their hardest, but not succeeding, then we need to assess if there is discouragement, or perhaps even the poison of cynicism. If that is the case, then the first treatment is not training, or a hot line, or disciplinary action, but the antidote of hope.

Hope, of course, is something that has been talked and written about from ancient times. It is important that the compliance officer understand what hope means to the organization's employees: an appreciation of their need for hope in order to be able to buy-in to a program that calls them to a higher level of ethics and behavior.

To motivate people in the billing office situation I described, you need to get them to change from within. You can change external behavior through training or disciplinary action, but this will not be a lasting change if people's hearts are not in it. But, if they can change from within, then you can ask people to use their freedom to make changes for the better. They will embrace the opportunity to do this, because they can develop a love for the work they are doing and for improving it, not just a tolerance. This makes all the difference in the world, and will help eventually to bring the enthusiasm mentioned at the start of this article.

How we can help

There is something in people that makes them want to do things the right way. It may lie dormant, or be numbed by cynicism, but it is there in most people, waiting to be awakened. By offering hope that things can be better, you can bring it out. It must be real hope, of course, not just naive idealism. Through belief that the hope is real and not just illusory, workers can have the courage to follow through to make changes, and to see them through to the end. And finally, hope must have a human face with a human heart.

In concrete terms, how do the elements of a compliance program bring hope to members of an organization? Well, face-to-face training, for example, not only gives people the tools to do their jobs better, it shows that the organization cares about the issues people face. The training must be done well and done with care—care that shows in the way it is presented—so that people can see that it is being done to help them do their jobs better, not just to fulfill a requirement.

A policy of listening to employees' qualms about questionable practices, in a way that leaves them free from fear of backlash, is freeing, because it gives them a sense of hope that things can be better. Listening on the part of managers is important, and employees often know more about the workings of the organization than managers do. Giving employees a hotline, in case they aren't comfortable that the non-retaliation policy will work, confirms that management really does want to hear about their issues and really does care. Actually doing something about the issues that are reported by employees or discovered by audits, by enacting positive

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Letter from the CEO

Ethics fun and games

I want to share with you some of the conversations that have been going on in the Ethics list serve on our Social Network. Almost a thousand people have now joined the Social Network. Travel is going to be tough in the next couple years. The budget cuts and economy are going to deter travel to conferences. You can sign up for the Social Network by going to our website. The conversation I am sharing below was conducted in the Ethics list serve. The Ethics list serve is one of about 40 to choose from, and if you don't see one you like, you can start your own. You can sign up for as many as you like.

Joe asked the following question:
What is the role of humor and games in compliance and ethics training? Some believe humor and games are valuable, because they capture employees' attention. Employee surveys typically rate these techniques highly. After all, if employees are otherwise dozing off during boring lectures, there is certainly no value to that.

But, is there a risk that employees may get too caught up in the fun part, and not remember the underlying message? I recall having this experience when I had an opportunity to play a Dilbert compliance game at a Defense Industry Initiative Best Practices Forum. All of us playing the game enjoyed it, but remembered little or nothing of the underlying message. While companies certainly want the training experience to be positive and memorable, it is also more than a popularity contest. And yet, humor can be very effective and memorable when used well. What is the right mix? And isn't it always best to test out training first to see what effect it actually has, and what employees actually take away from the training?

I had a rather cynical response:
If you are going to play ethics games, you should probably make sure you have a credible compliance program. If you talk about doing the right thing but don't enforce it, employees can become bitter. If management preaches ethical behavior but ignores problems, the people playing the ethics games may think it is a dishonest experience. If there are investigations, auditing, monitoring, discipline and reporting to the Board, then the games may help. If all you do is write a code of conduct and produce a video with the CEO telling everyone, "We are an ethical company," the ethics games could frustrate some people. They will think the effort lacks integrity. I see many organizations that put a majority of their time into these kinds of efforts and very little time into compliance. Employees who do not see an effort to root out problems and punish unethical behavior may not want to play these games.

Ted Banks had a more analytical response:
Humor or entertainment has a role in ethics training in two ways:

1. Cognitive learning: You want to make your transmission of facts to the learner as palatable as possible. So, this is the spoonful of sugar to make the medicine go down— you try to make the experience pleasant, but you don't let the sugar overwhelm the message.
2. Affective learning: You want to create the right attitude about compliance and ethics, and convey the message that the folks in this area are "good guys" and that it is cool to do the right thing. So, you want an approach that will set a tone for the area that will give employees comfort and provide them with the basis for the value system that is the foundation of any ethics program.

So, fun and games can provide a useful tool for both affective and cognitive learning, but they should be the method, not the message.

These interactions on the Social Network list serves are quite interesting. People recommend good books and share the latest news. Some of the best education comes at the breaks, lunches, and receptions of our meetings. People are able to explore ideas and concepts in a way that allows for immediate feedback. The list serves on the Social Network facilitate those types of conversations 24-7-365 from the comfort of your desk. These discussions allow people to build off each other's knowledge. New compliance and ethics concepts are created in the process. One person shares an idea, another comments, and together they generate an idea that neither would have gotten to on their own.

Join the Social Network today by going to the home page of our website (www.hcca-info.org). ■

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"Good fences make good neighbors"

By C. Elizabeth O'Keeffe, JD, MPH, LLM, CHC, CHSP

Editor's note: C. Elizabeth O'Keeffe is Senior Business Unit Counsel – PCMS, with a biopharmaceutical services company located in Waltham, Massachusetts. Ms. O'Keeffe may be reached by telephone at 781/434-4040 or by e-mail at elizabeth.o'keeffe@parexel.com.

The title is from the poem "Mending Wall" by Robert Frost[1]

The evolving relationship between in-house counsel and compliance professionals is one that is characterized by mutual interdependence and professional tension. What is the source of these independencies and tensions and how might they be leveraged to improve the relationship between the two? This article, the first of a two-part series, examines the origins of the practice of health care law and the compliance profession. Part 2 will explore pathways to a more productive and collaborative relationship.

The lawyer's view of the practice of health care law has origins in contract and tort law, as well as state law on professional licensure and municipal law (hospitals were typically owned by municipalities). I think many, if not most, health care lawyers chose this specialty to "help others" and may have been influenced by a close relative. Virtually every health care lawyer I know has either been a clinician or has a close relative who is a clinician. Some, though not I, considered becoming clinicians themselves and for one reason or another, chose the law instead.

By way of example, my father was a vascular surgeon in solo practice in Boston, Massachusetts. My grandfather was a general surgeon in a faculty practice associated with Tufts University and St. Elizabeth's Hospital in Brighton, MA. My impression of my grandfather's practice is that his time in medicine represented the "golden age" of medicine, where physicians were revered, if not respected, and the convergence of science and technology made the options for patients appear endless and professionally exhilarating.

My father, on the other hand, experienced the hardships of the practice of medicine. His solo practice demanded constant attention and management skills that he simply did not enjoy more than the surgical component. State and federal efforts to contain costs, increase access, and spread the risk for medical malpractice hit him squarely. For example, as a condition of licensure, he could not balance bill his patients for the costs of their care, notwithstanding the fact that he provided immeasurable charity care for the nuns and

priests in greater Boston and neighbors and friends. One year, he was required to pay a state-mandated malpractice premium that represented half of his annual net earnings. His anger at these perceived impositions upon him and his colleagues left an indelible impression in my mind. In fact, when I expressed an interest in law school, his direction was "to get out there and help us [the physicians] . . . we have no idea what is going on." He could not afford to send me to law school by then.

With that mandate in the back of my mind, I focused exclusively on locating a law school where health care law was considered a concentration, a specialty. At the time, Case Western Reserve University School of Law (CWRU) had one of the few recognized interdisciplinary programs in law and medicine, the Law-Medicine Center. It was established in 1953 and is led by the prolific and world-renowned health care law expert Professor Maxwell Mehlman, and Arthur E. Petersilge, professor of law and Director of the Law-Medicine Center at CWRU School of Medicine. I had the honor of studying all facets of health care law at CWRU and to write for its interdisciplinary journal, *Health Matrix*.

Back then, the focus of health care law practice was primarily upon bioethics (or, admittedly, these were some of the most interesting end-of-life cases, like Quinlan and Brophy), Medicare law, traditional corporate and transactional hospital and physician services law, and some nascent efforts to develop managed care systems. I distinctly recall going to interviews for my post-clerkship year and hearing, repeatedly, from law firms, "So you want to practice health care law – plaintiff or defendant?" Of course, it was commonly thought that the private practice of health care law then, for those not steeped in the specialty, meant you wanted to be a medical malpractice lawyer. That, however, was not my objective. No, young idealist that I was, I wanted to serve mankind, the public good, and unconsciously, all those doctors like my father who were overwhelmed by regulations and losing their grip on the traditional practice of medicine.

Note, I am not advocating that the "golden age" of medicine was indeed, the golden age. There are those with much more expertise than I have, as to the practice of medicine and its social evolution.[2] I am not suggesting that my father's feelings were, in the grand scheme of things, correct. Nonetheless, it influenced me tremendously in my chosen profession and specialty. When people you admire and respect become embittered or just give up altogether, it makes an unforgettable impression. You can see the pain, you can feel the professional

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attributes that we all hold dear start to wash away, bit by bit. The pride, the self-actualization, the respect—it all goes down the drain.

My practice back then, like those of many others I suspect, initially focused on risk management issues, medical staff disputes, contract matters, policies and procedures, accreditation issues, and patient care. "Compliance professionals" as we know them today, simply did not exist. To the extent that there were any, they typically were akin to consultants or regulatory specialists. My hard work paid off—I was now in a position to interpret those pesky regulations and assist my hospital and doctor clients to do what they did best—take care of patients while I attended to the paperwork, the burdensome side of the coin. Of course, my efforts didn't stave off my father's slow implosion; he died at the young age of 62, perhaps more as a result of his own personal issues than anything else. Of course, the disempowerment he had been feeling over the last fifteen years of his practice certainly didn't help his self-esteem.

By 1991, the now commonly known compliance initiatives like the US Sentencing Guidelines, industry compliance guidelines, Stark, EMTALA, HIPAA, the use of the False Claims Act, provider-based regulations, and others began their tumultuous onslaught upon the health care industry. Again, I am not suggesting that any of these initiatives isn't appropriate or needed. I am noting, however, that it changed my practice. I was no longer the avenger and proxy for my clients; I was the defender of the law. As an officer of the court, I took my oath very seriously. It was my job, first and foremost, to uphold the law. Yet, here came the Hospital Compliance Guidelines in 1998[3] and to my horror, the OIG didn't think that in my role as in-house counsel, I was honorable or able to uphold the law.

"The OIG believes that there is some risk to establishing an independent compliance function if that function is subordinance [sic] to the hospital's general counsel, or comptroller or similar hospital financial officer. Free standing compliance functions help to ensure independent and objective legal reviews and financial analyses of the institution's compliance efforts and activities. By separating the compliance function from the key management positions of general counsel or chief hospital financial officer (where the size and structure of the hospital make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program."[4]

Rather, compliance professionals were best suited for this. Pardon the colloquialism, but hello? I thought that was my job? I was trained for just that purpose, to advocate for my client, of course, but to uphold the law foremost. Who were these compliance professionals? What did they do that I did not?

Beyond affiliating with my own compliance officer at the time (who formerly had only had auditing experience and not for a health care facility) and learning the trade together, I joined the Health Care Compliance Association (HCCA). HCCA officially commenced in 1997. What better way to figure out what the professional domain of the compliance officer was than to go to conferences and meetings specifically targeting this group? What were they being taught about us untrustworthy lawyers anyway? I quickly found that compliance officers come in all stripes; they are generalists, financial experts, auditors, investigators, reimbursement gurus, former health care attorneys, and some are new to the field. In 2005, I was certified in health care compliance (CHC) by HCCA.

My first encounters with compliance folks were not always pleasant. In my experience, they didn't trust me and I thought they were trying to be lawyers without the accountability. Although I admit I was reticent at first and sensed that these compliance folks may well be encroaching upon my side of the fence, my feelings soon abated. I was immensely impressed by the quality of the folks at HCCA, the meetings, and the attendees. We all had different reasons for our interest in compliance, but we shared the common goal of serving our constituents.

HCCA's professionalism and credentialing programs made it all the more clear that not just anyone could claim that they were a "compliance professional." And for me, this made all the difference. In other words, I guess I felt a little resentful that all the expense and experience that I had put into my own professional development was, at least from the OIG's perspective, not very valuable. I found that frightening and, in a way, perhaps was harkening back to my father's dark days when he found that his professional attributes were under fire.

Since that time, I have had the opportunity to work with many compliance professionals and frankly, could not do my job without them. While the days of fighting for the title of "Chief Honesty Officer" are probably not over (the CEO? the MD? the JD? the COO?), I for one have found both sides of the fence equally professionally fulfilling. The common ground, not the fences, makes all the difference. ■

The opinions expressed are that of the author alone.

1 Available at: http://www.poemhunter.com/poem/mending-wall/
2 Starr, Paul: The Social Transformation of American Medicine. Basic Books (Perseus Book Group), 1982.
3 Available at: http://www.oig.hhs.gov/authorities/docs/cpghosp.pdf
4 Id. at Footnote 3


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Creating effective company-wide compliance training: Knowledge, awareness, and comprehension

By Audrey Brahamsha

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In the Medicare Advantage Prescription Drug Plan Sponsor Part D Audit Guide there are a series of requirements associated with a company's compliance plan. The first three of the nine elements are (1) compliance with federal and state standards, (2) designation of compliance officer and committee, and (3) effective compliance training. Our company established the second element first – the designation of the compliance officer. Our President and CEO, Steven J. Bory, designated Ms. Traci Kosak, who was the company's General Counsel, to be the compliance officer. It was then designated that the senior leaders of the company would be members of the Compliance Committee. Ms. Kosak developed the company's compliance program, in accordance with federal and state standards. She also spearheaded the development of corresponding policies and procedures.

For the effective training element, she came to me with her documents and requested the development of an effective training and education program for the company's employees. Her directive was to ensure that her compliance program was understood by all employees. This article will describe the lessons learned and the current best practice of our company.

The assignment

My first step in my assignment was to read the compliance officer's 32-page Compliance Program. I was distracted several times and lost my place even more times as my mind tended to drift off to more pleasant topics. Our compliance officer did an excellent job in developing a program based on federal and state standards, but the document was thick with definitions, rules, and regulations.

I was curious as to the readability level of this document. Because it was prepared in Microsoft Office Word, it was easy to click on the Tools menu, then Spelling and Grammar to get the document's readability scores. It was surprising to find out that the document had 10,200 words and a reading grade level of 15.9 (just about a senior level in college). Remembering college textbooks, I realized that of course it would be difficult to get through this document in one sitting.

I assessed the recipients of this required training: We have 500 employees in several different locations across the United States. We communicate with each other mainly by e-mail (Microsoft Outlook). The qualifications of the positions in our company ranged from "high school diploma required" to "college or masters degree preferred" to professional staff such as registered nurses, doctors, certified public accountants, and so on. The challenge was to develop one comprehensive training program for all staff in our organization.

The idea and the design

The initial step was to formulate an outline of the material to be covered. Here is an outline that worked well for our organization.

1. Compliance
   a. What does compliance mean?
   b. Why is compliance so important?
   c. Who is responsible for ensuring compliance?
   d. Who can you talk to regarding compliance?
2. Fraud and Abuse
   a. Definitions
   b. Related Statutes (Anti-kickback, EMTALA, False Claims, *qui tam*, Stark Law)
   c. Examples of non-compliance
3. HIPAA
   a. Definitions
   b. What is protected health information (PHI)?
   c. The company's Privacy Policy
   d. Examples of non-compliance
4. What you can do
   a. The company's Standards of Conduct
   b. Types of activities that should be reported
   c. The company's compliance hotline
   d. Consequences of non-compliance

This outline was used to develop clear statements and paragraphs covering the material. Instead of a Word document, Microsoft Office Publisher was used to develop a workbook with boxed definitions and colorful graphics with the objective that any employee could easily read, learn, and comprehend the material. This workbook became the company's self-paced, self-study program on compliance. To confirm the comprehension of the material in the workbook, there was a mandatory quiz at the end. Every employee

was required to complete the quiz and return it to me for pass/fail scoring.

The workbook was limited to a maximum of 20 pages, which included the cover page and the quiz sheet. In later years, we expanded the workbook to 25 pages, due to the changes and expansion of the regulations. On this page are a couple of sample pages from the workbook to give you an idea of the layout.

Before implementing the workbook process, the content of the workbook was approved by our compliance officer and then it was presented to our Compliance Committee where it was accepted for implementation.

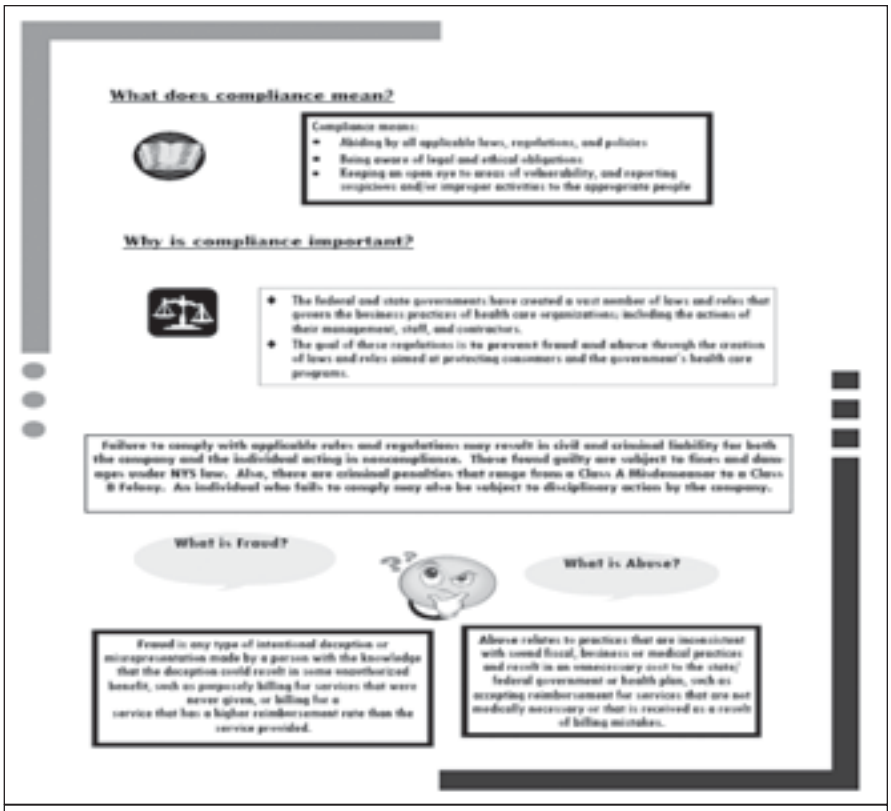
Timing of the process

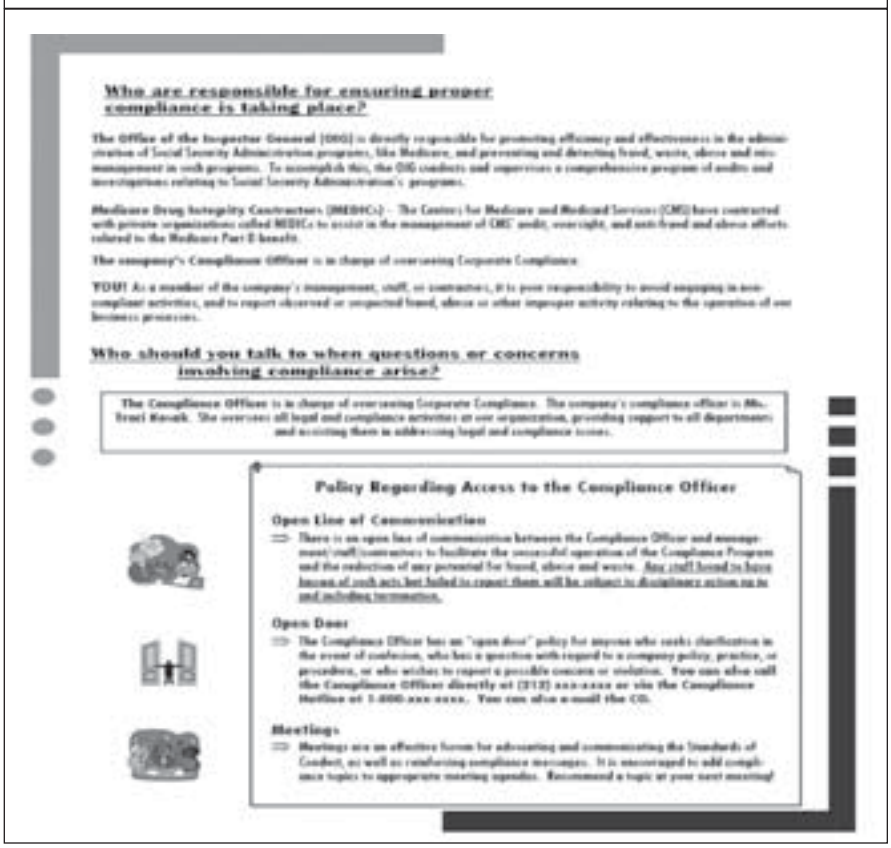
The roll-out of the first Compliance self-study process for our company took place in January 2006.

The process began with a company-wide e-mail announcement by our president and CEO, Steven J. Bory. His message was clear: Compliance is of utmost importance to maintain our company's stellar reputation in the marketplace. Mr. Bory alerted the staff about the distribution of the Compliance workbook and the need for the staff to read the material and complete the quiz.

The self-study process ended with the scoring of the last submitted quiz. This process, which was originally scheduled to be handled in a 3-week timeframe, took twice that time (6 weeks) to complete, and that was with many follow-up and reminder e-mails requesting completed quizzes from the staff.

In 2007, the second year of the self-study process (the workbook was updated and the quiz was changed), the process took even longer (8 weeks) to complete even though there was no change in the number of employees or the number of offices.





In 2008, our president and CEO allowed us to implement an incentive program for employees who submitted their completed quiz by a specific date and received a score of 90% or better. Those employees who scored in that range were

Continued on page 28

 ...continued from page 27

entered into a drawing for prizes, which were American Express gift certificates. We had three certificates to raffle. Due to this program, the process time improved to 5 weeks. Once again, an updated workbook and a different quiz were used, and there was with no notable change in the number of employees or offices.

The quiz questions

The quiz was a one-page set of questions covering the topics in the workbook. It had space for the staff member's name, office location, and date.

The first (2006) quiz had a wide variety of questions: multiple choice, true/false, matching concept to its definition, and open format (essay) questions. The open format questions were the hardest to grade for reasons related to the employee's penmanship as well as my consternation in determining whether the answer was completely correct or partially correct. Although it is recommended to use multiple-choice and true/false questions (if only for the ease and sanity of the person who will be hand-grading these quizzes), it really is very interesting to read the answers to the write-in questions. With that said, in 2008 all questions on our quiz were multiple-choice.

Some quiz questions turned out, surprisingly, to be difficult.

Who is responsible for ensuring proper compliance is taking place?

a. The company's Compliance Officer
b. All members of the company's management, staff, and contractors
c. The Office of the Inspector General
d. All of the above

The correct answer was D, but 50% of the respondents picked selection A. I attributed this selection to the person's not reading the entire question before answering.

Some questions were obviously (too) easy:

Who should you talk to if you become concerned that there has been a failure in compliance with federal/state laws, health care programs, or ethical standards?

a. Mr. George Bush, President of the United States
b. Ms. Traci Kosak, Compliance Officer
c. Mr. Daniel R. Levinson, Inspector General of the Department of Health and Human Services
d. Integriguard, LLC (Medicare Drug Integrity Contractor for CMS)

The correct answer is B and 100% of the staff got this correct.

Open format questions were used in the 2006 and 2007 quizzes, and the answers were very revealing as to the comprehension of the material by the employee. Here are some questions that were used.

In your own words, define fraud.

_____

In your own words, define the Anti-kickback Statute

_____

Give three examples of information that is considered individually identifiable health information protected by HIPAA

_____

_____

_____

Provide an example of non-compliant conduct that should be reported

_____

The 2006 self-study workbook contained page called "In the News" which detailed some of OIG's investigations and identifications of fraudulent activities.

A true/false question related to this page proved to be confusing to many employees. The answer was "False" and many employees got this incorrect.

The Office of the Inspector General has not sanctioned any company/person for fraud, waste or other activities that were a threat to Federal health care programs and beneficiaries.

A. True
B. False

After discussions with a few employees who answered this question incorrectly, it was ascertained that the confusion in the question was attributed to the word "sanctioned." This word can mean "authorize" as well as meaning "penalize." I checked the American Heritage Dictionary, (Third Edition, Houghton Mifflin Company, 1997, pages 1206-1207) for the definition. There were two, one for the word used as a transitive verb and another for the word used as a noun. The question was not reused in future quizzes.

Sanction, transitive verb:

1. To give official authorization or approval to
2. To encourage or tolerate.

Sanction, noun:

1. Authoritative permission
2. Support or encouragement
3. A consideration, an influence

4a. a law or decree
4b. the penalty for non-compliance specified in a law or decree

5. A penalty
6. A coercive measure.

The quiz results

In 2006, 92% of the staff passed with their first attempt at the quiz. Staff was permitted to retake the quiz until they succeeded at passing.

In 2007, 97.5% of the staff passed with their first attempt at the quiz, and we continued to

allow the staff who failed to re-take the quiz until they succeeded at passing. The 2007 quiz sheet is shown below.

As previously mentioned, in 2008, our president and CEO allowed us to implement an incentive program for employees who scored 90% or better on the quiz. We had three gift certificates to raffle. With this incentive, 90% of the staff scored 90% or better on their compliance quiz. More importantly, all staff members passed the quiz on the first try.

Conclusion

Our compliance officer's original Compliance Program had 10,200 words and a reading grade level of 15.9. The Compliance Workbook captured the content of the Compliance Program in 3,609 words and had a reading grade level of 8.0 (grammar school level). Our company's Compliance Committee considers the Compliance Workbook a success in educating our employees. ■

CONGRATULATIONS FOR COMPLETING THE TRAINING MANUAL!

Now Quiz Yourself! (Choose the best answer to each question. After completing the quiz, remember to send it to Audrey Brahamsha.)

Please circle the correct answer.

1. Who is responsible for ensuring proper compliance is taking place?
   a.) The company's Compliance Officer (CO)
   b.) The Office of the Inspector General (OIG)
   c.) All members of the company's management, staff, and contractors
   d.) ALL OF THE ABOVE

2. If you become concerned that there has been a failure in compliance with federal/state laws, health care programs, or ethical standards, which action listed below is NOT appropriate to take?
   a.) Calling the Compliance Hotline and to report your concerns anonymously
   b.) Keeping your suspicions/concerns to yourself. After all, you are not the one who is failing to comply
   c.) Stopping by the Compliance Officer's office to speak with her in person regarding your concerns
   d.) Calling the Compliance Officer at her number and extension

3. Which of the following conduct is required according to Royal/NHP's "Standards of Conduct"?
   a.) Participating in training and education programs regarding compliance
   b.) Understanding that ignorance is not an excuse for noncompliance
   c.) Being committed to high quality health care and service delivery
   d.) ALL OF THE ABOVE

Please match the following list of laws with the correct definition. (List the letter of the law on the line next to the definition)

A. False Claims Act
B. HIPAA Statute
C. Anti-Dumping Statute (EMTALA)
D. Anti-Kickback Statute

4. ____ This statute prohibits the use or disclosure of protected health information unless it is permitted or required by the statute.
5. ____ This statute may be violated when someone intentionally trades referrals for items/services payable by a Federal health program for something of value (like bribes, rebates, cash).
6. ____ You can be held liable under this statute, if you knowingly make a false statement to conceal overpayment by the government, even if the overpayment was the error of the government.
7. ____ This statute requires that if any person comes to the emergency room of a hospital and requests treatment, the hospital must perform an appropriate medical screening without delay.

Please indicate whether the statements below are TRUE or FALSE.

8. Compliance requirements may affect both your activities at work and also communications you have outside of the office.
   a.) TRUE
   b.) FALSE

9. If a staff member receives an investigative demand, subpoena, or search warrant involving Royal/NHP, staff may release or copy any documents without authorization from the CO or legal counsel.
   a.) TRUE
   b.) FALSE

10. Failure to comply with the "Standards of Conduct" promulgated by Royal/NHP may result in oral or written warning, disciplinary probation, suspension, reduction in salary, demotion, dismissal from employment, revocation of network privileges and contract termination.
    a.) TRUE
    b.) FALSE

11. In the space below, provide an example of noncompliant conduct that should be reported: (3 points)

    _____

    _____

12. In the space below, give three examples of information that is considered individually identifiable health information, protected by HIPAA. (3 points)

    1. _____
    2. _____
    3. _____

Name: _____
Title: _____
Department: _____
Office Location: _____
_____
Date: _____

feature focus

DOJ changes its rules for assessing corporate cooperation

By R. Christopher Cook and Joseph W. Clark

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The Department of Justice (DOJ) has amended significantly its official position regarding the corporate attorney-client privilege and the manner in which it expects organizations to treat employees suspected of wrongdoing. These changes, announced by Deputy Attorney General Mark Filip on August 28, 2008, promise to have a profound effect on the manner in which organizations are treated by the DOJ when employees are alleged to have violated the law. Under these new guidelines, organizations should have a greater ability to investigate potential wrongdoing without fear that legitimately privileged communications will be subject to a forced waiver. Likewise, organizations should be free to treat employees fairly when deciding whether to pay for their legal costs or continue employment while an investigation is pending, confident that such equitable treatment will not be seen by the DOJ as a sign of obstruction.

This new approach by DOJ is welcome news for the health care industry, whose organizations have been the subject of a disproportionate number of criminal investigations in the last decade. As with other organizations that have been the target of DOJ investigations recently, health care companies often have been the subject of heavy-handed tactics. Prosecutors have routinely demanded waivers of the attorney-client privilege as a condition of treating an organization as "cooperative" in an investigation, while also insisting that employees accused, but not convicted, be cut loose from all financial support. The long-term consequences of such policies are predictable—erosion of the privilege, an inability of corporations to seek counsel for fear of having those communications breached, and employees forced to plead guilty rather than face financial ruin from defending a complex white collar criminal investigation.

Coincidentally, the need for these new guidelines was echoed by a decision issued on the same day by the Second Circuit Court of Appeals, only blocks away from where Deputy Attorney General Filip was speaking before the New York Stock Exchange. The decision in *United States v. Stein*,[1] (the "KPMG Decision") held that certain tactics by the DOJ in its investigation of allegedly illegal tax shelters violated the rights of the individual defendants, violated the Constitution, and required the dismissal of the charges against them. Those tactics are now prohibited under the new DOJ guidelines, including the practice of pressuring an organization to refuse payment of legal fees in an attempt to squeeze employees into cooperating.

The implication of this new policy for counsel and compliance officers is clear: Internal investigations can now be structured with greater predictability regarding what is confidential and what will be subject to disclosure to the government. Generally speaking, organizations can seek the advice of counsel with reasonable assurances that those conversations will be protected by privilege. To the extent that the organization conducts an internal investigation—a decision itself that should be informed by confidential advice of counsel—it should be aware that the facts uncovered in that inquiry must be disclosed to the government if the organization ever seeks credit from the DOJ for cooperating fully in an investigation. Even if the decision is made to cooperate, the issue of whether, when, and how to discipline employees, including whether to pay their legal fees while an investigation is pending, will remain within the discretion of the organization itself.

DOJ policy for evaluating corporate cooperation

It is instructive to examine how the DOJ policy for evaluating

corporate cooperation has evolved over the last decade. What follows is a brief history of the memoranda issued by DOJ regarding waiver of attorney-client privilege and corporate contractual arrangements to advance attorneys' fees to employees under investigation.

The Holder Memorandum

DOJ's practice of announcing formal guidelines for how it would handle corporate prosecutions, including assessments of cooperation, began approximately nine years ago. On June 16, 1999, then-Deputy Attorney General Eric Holder issued a memorandum entitled "Federal Prosecution of Corporations" (the Holder Memo). The Holder Memo established factors that prosecutors should consider when determining whether to charge a corporation. One factor in particular required prosecutors to consider "the corporation's cooperation and voluntary disclosure." Specifically, the Holder Memo explained:

> In determining whether to charge a corporation, that corporation's timely and voluntary disclosure of wrongdoing and its willingness to cooperate with the government's investigation may be relevant factors. In gauging the extent of the corporation's cooperation, the prosecutor may consider the corporation's willingness to identify the culprits within the corporation, including senior executives, to make witnesses available, to disclose the complete results of its internal investigation, and to waive the attorney-client and work product privileges.[2]

This was the first time that official DOJ policy called for waiver of the attorney-client privilege as a condition of lenient treatment.

The Holder Memo created a sea change in federal corporate prosecution. Traditionally, prosecutors would issue grand jury subpoenas and investigate corporations from the outside. Cooperative corporations would often assist the government in uncovering wrongdoing, but very seldom shared privileged communications or the results of internal investigations. If a privilege waiver was requested, it almost always was limited in scope and came at the end of the investigation. After the Holder Memo, however, prosecutors began seeking broad waivers of the attorney-client privilege and work product protection with increasing regularity. Moreover, these requests were being made at the beginning of an investigation.

Further, the Holder Memo's emphasis on a "timely" disclosure created a conundrum for corporations. Although the government asserted that a corporation was not required to waive any privilege or work product protection, the prosecutors sometimes viewed the corporation's failure to disclose privileged information as an effort to conceal otherwise incriminating facts. And, to make a timely disclosure, counsel for corporations often felt compelled to waive the privilege at the outset of an investigation in order to meet the government's expectation of timeliness. This practice threatened to turn counsel for a corporation into agents for the government's investigation. Counsel for corporations, whether in-house or outside counsel, would conduct an internal investigation, gather documents and notes, and interview witnesses – all the while knowing that the results of the investigation would be turned over to the federal government so that the corporation could either avoid prosecution or be charged with a lesser offense.

In response to the government's demands for employee statements, corporate counsel developed the practice of conducting internal investigations, warning employees that their statements might (or would) be provided to the government if the corporation decided to waive the attorney-client privilege. These warnings in turn created the risk to employees that any misstatements to counsel would themselves be prosecuted as false statements to the government. Indeed, in September 2004 the DOJ famously obtained guilty pleas from three executives based on allegedly misleading statements they had made to counsel conducting an internal investigation.[3]

The Thompson Memorandum

DOJ continued to refine its policies regarding corporate cooperation and, in January 2003, then-Deputy Attorney General Larry Thompson distributed a memorandum entitled "Principles of Federal Prosecution of Business Organizations" (the Thompson Memo). The Thompson Memo reinforced the policy articulated in the Holder Memo and established a binding model for prosecutors to use in evaluating corporate conduct and deciding whether to bring charges against a corporation. Under the Thompson Memo, corporations perceived as not fully cooperating with a government investigation were more likely to face prosecution.[4] Compared to the Holder Memo, however, the Thompson Memo advanced deeper into the corporation's relationship with its employees and attorneys.

Among other factors, the Thompson Memo instructed prosecutors to weigh the extent and value of a corporation's cooperation by assessing the completeness of the corporation's disclosure

> "including, if necessary, a waiver of the attorney-client and work product protections, both with respect to its internal investigation and with respect to communications between specific officers, directors and employees and counsel."

Continued on page 34

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Further, prosecutors were directed to consider whether the corporation "appears to be protecting its culpable employees and agents" through "the advancing of attorneys' fees." Effectively, the Thompson Memo required corporations to give the government unprecedented access to privileged and potentially inculpatory statements while refusing the advancement of attorneys' fees to employees whom the government considered to be culpable and non-cooperative.

The Thompson Memo created a practical dilemma for many corporations with respect to advancing attorneys' fees and protecting attorney-client communications. First, the corporation was put in the untenable position of deciding which employees were culpable and which were cooperative. Or, more accurately, the corporation was forced to predict whether advancing attorneys' fees to individual employees accused of wrongdoing would be perceived by the government as "protecting its culpable employees and agents," as the Thompson Memo discouraged. This desire to protect the corporation often clashed with the desire to treat employees with fairness and a presumption of innocence. It also ran the risk of leaving employees without access to legal advice on matters crucial to the corporation's continued well-being.

As to the attorney-client privilege, the Thompson Memo's broadened demand for waiver ran the risk of turning corporate counsel into witnesses in future criminal proceedings. Whereas the Holder Memo focused on waiver of the privilege as to internal investigations, the Thompson Memo explicitly called for waiver of prior communications with counsel. From DOJ's perspective, such communications could provide evidence to show that individual executives or other employees had knowledge that certain actions were or may be unlawful. Waiver of the corporation's privilege, therefore, made it easier for DOJ to convict such individuals, using corporate counsel as a witness at trial. From the corporation's perspective, however, the specter of future waiver made it less likely that individuals would consult with corporate counsel on risky behavior for fear that such an inquiry would itself be evidence of wrongdoing.

The McNulty Memorandum

The DOJ received much criticism for its policies on corporate prosecutions under the Thompson Memo. Accordingly, on December 12, 2006, Paul J. McNulty, then-Deputy Attorney General, revised the policies by issuing the so-called McNulty Memo.[5] The McNulty Memo contained the same nine broad factors articulated in prior iterations of the DOJ's policy on charging corporations. But, the McNulty Memo made significant changes to the two portions of the Thompson Memo relating to the production of privileged materials and consideration of the corporation's payment of attorneys' fees for employees.

With regard to privileged materials, the McNulty Memo authorized prosecutors to request privileged material only "when there is a legitimate need for the privileged information to fulfill their law enforcement obligations." The McNulty Memo affirmed that there must be

> "a careful balancing of the important policy considerations underlying the attorney-client privilege and work product doctrine and the law enforcement needs of the government's investigation."

To accomplish this balance, the McNulty Memo recognized two categories of privileged materials. Category I materials consisted of

> "copies of key documents, witness statements, or purely factual interview memoranda regarding the underlying misconduct, organization chart created by company counsel, factual chronologies, factual summaries, or reports (or portions thereof) containing investigative facts documented by counsel."

To request Category I materials, prosecutors were required to secure approval from the United States Attorney in consultation with the Assistant Attorney General for the Criminal Division. Approval would be granted when the prosecutor demonstrated a legitimate need for the information and set forth the scope of the waiver sought.

By contrast, Category II materials included "attorney-client communications or non-factual attorney work product," including "legal advice given to the corporation before, during, and after the underlying misconduct occurred." Examples of Category II materials included

> "attorney notes, memoranda or reports (or portions thereof) containing counsel's mental impressions and conclusions, legal determinations reached as a result of an internal investigation, or legal advice given to the corporation."

Prior to requesting Category II materials, prosecutors were required to secure the approval of the U.S. Attorney in consultation with the Deputy Attorney General for the Criminal Division. Overall, the McNulty Memo made clear that prosecutors should seek Category II materials in rare circumstances and were not permitted to consider a corporation's decision to withhold Category II materials when determining whether to charge the corporation.

In assessing corporate cooperation, the McNulty Memo reversed the government's position on the issue of attorney fees. Previously, prosecutors were permitted to weigh or consider whether the corporation appeared to be protecting culpable employees and agents through the payment of attorney fees. Pursuant to the McNulty Memo, however, "prosecutors generally should not take into account whether a corporation is advancing attorneys' fees to employees or agents under investigation and indictment." Rather, the McNulty Memo stated that

> "in extremely rare cases, the advancement of attorneys' fees may be taken into account when the totality of the circumstances show that it was intended to impede a criminal investigation."

In recognition of a corporation's obligation under state law or contractual arrangements to advance attorneys' fees, the McNulty Memo concluded that such payments "cannot be considered a failure to cooperate."

Revisions to the United States Attorneys' Manual

In response to each iteration of the DOJ's policy regarding the charging of corporations, Congress and the business and legal communities placed increasing pressure on the DOJ to ensure that corporations were not forced to waive the protections of the attorney-client privilege and the work product doctrine in order to receive full cooperation credit in a DOJ investigation. In an open letter to then-Attorney General Alberto Gonzales in May 2006, the American Bar Association criticized the practice and called for a revision of the policy.[6] Two years later, in July 2008, Attorney General Michael Mukasey acknowledged in his testimony before the U.S. Senate, Judiciary Committee, that the DOJ would no longer measure cooperation by waiver of the attorney-client privilege. Members of the Senate Judiciary Committee were skeptical. In particular, Senator Arlen Spector questioned the justification for coercing a waiver of the privilege and raised the possibility that legislation may be necessary. To that end, Senator Spector has introduced legislation that would expressly prohibit U.S. Attorneys or agents, within all federal agencies, from considering a valid assertion of the attorney-client privilege or attorney work product in deciding whether to treat an organization or person as cooperative.

By now it was clear that Congress was on the verge of taking from DOJ significant aspects of its discretion in evaluating corporate cooperation. It was thus no surprise that, on August 28, 2008, Deputy Attorney General Mark Filip announced comprehensive changes to the factors prosecutors may consider in determining whether to bring charges against a corporation. Underscoring the significance of these changes, Deputy Attorney General Filip declined to issue the policy in the form of a memo bearing his name. Instead, the DOJ committed the revisions and policy changes to the United States Attorneys' Manual, which is binding on all federal prosecutors within the Department of Justice. The revisions and policy changes became effective immediately.

The August 2008 Revision reflected dramatic departures from the McNulty Memo with regard to

(1) the attorney-client privilege and the work product protection;
(2) the treatment of Category II materials described above;
(3) the advancement of attorneys' fees;
(4) the existence of a joint defense agreement and the treatment of employees accused of wrongdoing; and
(5) requests for certain categories of information.

First, the August 2008 Revision seeks to reverse the perceived erosion in the attorney-client privilege and the work product protection that occurred under prior iterations of the DOJ's policy on whether to charge corporations. The DOJ recognized that its position on "attorney-client privilege and work product protection waivers promoted an environment in which these protections are being unfairly eroded to the detriment of all.[7] Prosecutors are now explicitly forbidden from conditioning cooperation credit on waiver of attorney-client privilege or work product protection. Rather, the government's key measure of cooperation is whether the corporation has "timely disclosed the relevant facts about the putative misconduct" not "whether the corporation discloses attorney-client or work product materials."[8] Under the August 2008 Revision, corporations receive the same credit for the timely disclosure of facts not otherwise protected as it would for disclosing identical facts contained in protected materials.

Second, the August 2008 Revision prohibits prosecutors from requesting the disclosure of non-factual attorney-client communications and attorney work product. In other words, DOJ will not under ordinary circumstances demand that corporations reveal the advice given by counsel to officers, employees, or directors. The government recognized that these communications lie at the core of the attorney-client privilege and can facilitate "a corporation's effort to comply with complex and evolving legal and regulatory regimes." Accordingly, the August 2008 Revision expressly authorizes a corporation to decline disclosure of these communications except where the corporation or one of its employees asserts an advice-of-counsel defense or the communication is in furtherance of a crime of fraud (both of which are rare and time-honored exceptions to the attorney-client privilege).

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HCCA's Managed Care Compliance Conference provides essential information for individuals involved with the management of compliance at health plans. See agenda below

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Sunday, February 22

Effective Self-Disclosure
Matt Weber, Partner, Holland & Hart LLP
Gregory J. Wellins, Senior Counsel, Office of Counsel to the Inspector General, U.S. Department of Health and Human Services

Development of a Compliance Plan
Jason Hall, Interim Regional Compliance Officer, Hawaii Region, Kaiser Permanente

Training for the Workforce and the Use of Technology
Brett Curran, Vice President GRC and Regulatory Practices, Axentis, Inc.

Medicare D 101
Dorothy DeAngelis, Managing Director, Huron Consulting Group
Libby Easton-May, Manager, Huron Consulting Group

Monday, February 23

Hot Topics from the Centers for Medicare and Medicaid Services
Kim Brandt, Director Program Integrity Group, Center for Medicare and Medicaid
Brenda Tranchida, Program Compliance and Oversight Group, Center for Drug and Health Plan Choice, Centers for Medicare and Medicaid Services

Risk Assessment: The Good, the Bad, and the Ugly
Steve Bunde, CPA, CFE, CHC, Sr. Director of Corporate Integrity & Internal Audit, Health Partners
Deb Ziegler, Corporate Compliance Officer, Capital Blue Cross

Preventing and Responding to Data Breaches
Anne Doyle, Executive VP/ Chief Compliance Officer, Fallon Community Health Plan

Regulatory Reports and Submissions: Just What Are You Sending To Your Customer?
Gary Fitzgerald, Director Compliance & Regulatory Affairs, Harmony Health Plan of IL

Effectively Structuring a Strong Fraud, Waste, and Abuse Program
William Gedman, VP Audit, Fraud & Abuse UPMC Health Plan

Information Security for Health Plans
Jeannette Frey, Privacy Officer, Fallon Community Health Plan

Oversight of Your Vendors for Medicare Advantage and Part D Business
Annmarie Gover, Medicare Compliance Officer, Capital BlueCross

Medicare Advantage and Part D Compliance Best Practices
Christian Presley, Compliance Officer, Blue Cross Blue Shield of Massachusetts
Lucia Giudice, Director, Healthcare Advisory Practice, PricewaterhouseCoopers

Medicaid Managed Care: Creating and Managing Effective Compliance Programs Including Compliance Auditing and Responding to Managed Care Fraud
Linda Tomaselli, Partner, Epstein Becker & Green PC
Elizabeth Browning, CHC, Compliance Manager, Fallon Community Health Plan

Tuesday, February 24

NYS–OMIG Compliance Guidance for Medicaid Managed Care
Jim Sheehan, Medicaid Inspector General, New York State Office of the Medicaid Inspector General

The Top Ten Compliance Challenges for Managed Care Plans
Kirk Nahra, Partner, Wiley Rein LLP

Compliance and Your Health Plan Sales
Lori Dutcher, Vice President Compliance MSSA, Kaiser Foundation Health Plan

Compliance, Internal Audit, and Legal: An Independent, Integrated Approach
Rebecca Learner, Senior VP & Compliance Officer, SCAN Health Plan

Plans and Involving the Board
Dan Garcia, Senior Vice President, Kaiser Permanente

Mind Your Own Business… Associates: Detailed Guidance For Creating and Implementing a Successful Business Associate Assessment Program
Sharon Anolik, Blue Cross Blue Shield of CA

Medicare Advantage and Part D Oversight Activities: A Health Plan Perspective
Kim Green, Compliance Officer, Blue Cross and Blue Shield Northern Plains Alliance
Sandra Miller, Director of Government Compliance, Blue Cross Blue Shield of MN

Key Litigation Risks for Health Plans
Rick Shackelford, Partner, King & Spalding

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Third, with regard to attorneys' fees, the August 2008 Revision limits the circumstances under which a prosecutor may ask about an attorney's representation of a corporation or its employees, officers, and directors. A prosecutor may ask questions regarding attorney fees when such an inquiry is permitted under the law or if the payment of attorney fees constitutes criminal obstruction of justice. Otherwise, prosecutors may no longer consider whether a corporation is advancing or reimbursing attorney fees or providing counsel to its employees under investigation or indictment. This policy shift is consistent with the Second Circuit Court of Appeals unanimous rejection of the prior practice under the Thompson Memo as a violation of a defendant's constitutional right to counsel in *United States v. Stein*.

Fourth, in assessing cooperation, the August 2008 Revision removes from consideration whether the corporation has entered into a joint defense agreement or whether the corporation has disciplined or terminated its employees. The government may consider company action against employees only in assessing the strength of the corporation's compliance program and remedial measures, or the sufficiency of its internal controls. These factors are relevant to the government's charging decision as opposed to an assessment of whether the corporation is cooperating with the government.

A final distinction between the McNulty Memo and the August 2008 Revision centers on a prosecutor's access to certain categories of information. As discussed above, the McNulty Memo required prosecutors to secure approval from the United States Attorney in collaboration with the Assistant Attorney General for the Criminal Division prior to requesting certain types of information from a corporation. Because the August 2008 Revision forbids requests for most of the information previously accessible, the policy no longer contains a process for federal prosecutors to secure approval from Main Justice. Instead, the policy encourages defense counsel to report violations of the new policy to the local United States Attorney or the appropriate Assistant Attorney General.

The August 2008 Revision will have a foreseeable and immediate impact on how corporations respond to investigations by DOJ. No longer are corporations required to waive attorney-client privilege and refuse to support employees with legal counsel. Instead, companies have the flexibility to investigate allegations of wrongdoing responsibly and to fashion ways to cooperate with the government that will protect the attorney-client privilege. Perhaps most importantly, corporations have received greater assurance that the advice attorneys provide to their officers, directors, and employees will remain confidential in all but the most extraordinary circumstances. This confidentiality lies at the heart of the privilege and can now continue to encourage frank and full discussions with corporate counsel.

Continuing risks and considerations

To the extent that a corporation is seeking to obtain credit for cooperation under this new DOJ policy, some words of caution are in order. Even under these revised policies, corporations face some risk of waiver arising from the disclosure of relevant facts gathered through an attorney-led internal investigation. Such a disclosure, even if carefully designed to avoid revealing privileged communications, may weaken a future claim of privilege or assertion of work product protection in later civil litigation. For example, the disclosure to the government of facts learned during an attorney's interview of a corporate employee may result in a claim that any privilege or protection has been waived for other aspects of the employee interview or with regard to the underlying subject matter.

Counsel for corporations also must pay close attention to joint defense agreements to make certain that they do not contain provisions that could prove problematic under this new policy. For example, the August 2008 Revision continues to emphasize the "timely" disclosure of relevant facts, and obligations assumed under a joint defense agreement could conceivably interfere with the timing of such a disclosure. In addition, the government might still penalize a corporation for sharing with third parties information it has acquired from the government during the course of the company's cooperation, even if such sharing was mandated by a joint agreement. Conversely, if a joint defense agreement limits the information the corporation can provide to the government, the government might not consider the corporation fully cooperative.

And, when a corporation discovers misconduct, it must act appropriately in its relationship with its employees. Under the August 2008 Revision, when a corporation seeks credit for cooperating with the government, the DOJ will still scrutinize the adequacy of its compliance program. The DOJ has made clear that the discipline meted out to employees who have engaged in misconduct—up to and including dismissal—remains a factor the government will consider in evaluating the strength of the company's compliance program. The fact that such discipline can no longer be used as leverage by DOJ does not lessen the corporation's responsibility to discipline employees for illegal conduct.

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DOJ changes its rules for assessing corporate cooperation

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The KPMG Decision

The importance of the DOJ's new policies was reinforced by a landmark decision issued on the same day as Deputy Attorney General Filip's announcement. In *United States v. Stein*, the Second Circuit rejected as unconstitutional the government's interference with the defendants' right to counsel in the form of advancement of legal fees from their employer, KMPG. Specifically, the circuit court held that the government inappropriately influenced KPMG to adopt and enforce a policy under which KPMG "conditioned, capped, and ultimately ceased advancing legal fees to defendants."[9] The court found that KPMG's conduct amounted to state action and that the government had "unjustifiably interfered with defendants' relationship with counsel and their ability to mount a defense, in violation of the Sixth Amendment." The circuit court unanimously affirmed the district court's extraordinary remedy of dismissing the indictment against the former KPMG partners and employees.

The indictment of these KPMG employees stemmed from the government's investigation of the firm's possible involvement in creating and marketing fraudulent tax shelters. The timing of the government's investigation coincided with the application of the Thompson Memo, which directed prosecutors to inquire about a corporation's protection of culpable employees "through the advancing of attorneys fees," among other factors. According to the Second Circuit, KPMG learned in February 2004 that the firm along with 20 to 30 of its top partners and employees were subjects of the grand jury investigation of fraudulent tax shelters. KPMG elected to cooperate with the government's investigation. In a 2004 memorandum to all partners, KPMG's CEO acknowledged the existence of the government's investigation and, consistent with its partnership structure, advised KPMG partners that "[a]ny present or former members of the firm asked to appear will be represented by competent coun[sel] at the firm's expense." KPMG also opted to advance legal fees to counsel for employees whom the government interviewed or subpoenaed to appear before the grand jury.

The parameters of KPMG's cooperation were negotiated through a series of meetings and memorialized in notes and in correspondence between counsel for KPMG and

the government. The advancement of attorney's fees became a focal point in these negotiations as the government insisted that culpable employees should not receive a benefit for their "misconduct" under the "federal guidelines." The court found that the government had used the prospect of indictment—fatal to an accounting firm—to force KPMG to adopt and apply a policy that conditioned the payment of attorney fees on cooperation with the government. (Factually, the district court also found that the government used KPMG to discourage employees from retaining counsel at all.) Specifically, KPMG conditioned payment of attorney fees on cooperation, capped attorney fees at a certain amount, and terminated the payment of attorney fees for any employee who refused to be interviewed, or who was subsequently indicted.

To implement this policy, KPMG invited the government to inform KPMG counsel whenever an employee had failed to cooperate with the government's investigation. The court found that over the course of the government's investigation, whenever the government complained that an employee had failed to cooperate, KPMG advised counsel for the employee that KPMG would stop advancing attorney fees if the employee did not cooperate. KPMG also made clear to the government and to employees its intention to terminate any employee who failed to cooperate. By acquiescing to the government's pressure, KPMG obtained a Deferred Prosecution Agreement with the government in August 2005. The agreement required KPMG to continue its cooperation with the ongoing investigations and prosecutions of its employees. Otherwise, KPMG would lose the benefit of the agreement and face indictment.

Meanwhile, the government indicted a number of KPMG employees. It was these defendants who subsequently challenged the government's conduct as unconstitutional. Specifically, the employees moved to dismiss the indictment on the grounds that the government's conduct deprived them of their right to counsel in violation of the Sixth Amendment and their right to due process in violation of the Fifth Amendment. The district court agreed and dismissed the indictment; the circuit court affirmed. Effectively, the circuit court's decision repudiates the government's prior practice of considering the advancement of attorney fees as a factor in measuring cooperation. That practice, of course, has now been abandoned under DOJ's new policies.

Pending legislation

As noted above, DOJ's policies regarding the corporate attorney-client privilege also have resulted in legislative initiatives. At least one such bill now pending in Congress may yet become law.

On November 13, 2007, the U.S. House of Representatives passed H.R. 3013, the Attorney-Client Privilege Protection Act of 2007, to provide appropriate protection to assertions of attorney-client privilege and attorney work product.[10] The House bill prohibits U.S. Attorneys or agents from considering five factors in determining whether an organization or person is cooperating with the government:

(1) a valid assertion of the attorney-client privilege or attorney work product;
(2) the advancement of attorney fees and expenses of an employee;
(3) entry into a joint defense, information-sharing, or common-interest agreement with an employee;
(4) the sharing of relevant information with an employee; and
(5) failure to terminate or sanction an employee who has exercised a constitutional right or legal protection in response to a government request.

Senator Arlen Spector introduced a similar measure, the Attorney-Client Privilege Protection Act, on June 26, 2008.

Even before the August 2008 Revision was issued by DOJ, Senator Specter signaled that legislation might be unavoidable. In a July 10, 2008 letter to Deputy Attorney General Filip, Senator Spector questioned whether it was sufficient to measure cooperation on the facts and evidence provided when such facts or evidence may have been obtained from individuals who were relying on the attorney-client privilege when they disclosed certain facts or information to counsel.[11] Recognizing the possibility that factual and non-factual attorney work product may overlap, Senator Spector explained that the government's proposed revision failed to address this area. Further, Senator Spector questioned the relevance of joint defense agreements and adverse employee action in measuring cooperation. Before closing his letter, Senator Spector expressed concern that the proposed revisions could be subject to modification by any subsequent Attorney General and were not binding on other federal agencies.

Following the announcement of DOJ's revised policies, Senator Specter again expressed his concern that DOJ's changes do not go far enough. In his August 28, 2008 statement responding to the revised guidelines, Senator Spector recognized that the revisions were "a step in the right direction" but were lacking in several respects.[12] Senator Spector stated, by way of example, that "there is no change in the benefit to corporations to waive the privilege by giving facts obtained by corporate attorneys from individuals in order to escape prosecution or to have a Deferred Prosecution Agreement."

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DOJ changes its rules for assessing corporate cooperation

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As compared to the DOJ's revisions, the proposed legislation would strengthen the attorney-client privilege by expressly forbidding government counsel or agents from considering a valid assertion of attorney-client privilege or attorney work product. Similarly, the proposed legislation does not restrict a corporation's ability to share information it has received from the government with others who are a part of a joint defense agreement or common-interest agreement. Further, the government would be prohibited from assessing employee termination or sanction as a measure of cooperation. Importantly, Congressional legislation would have a binding effect on government agencies other than DOJ, none of which are bound by the August 2008 Revision.

How corporations should respond

DOJ's revisions to its corporate charging guidelines provide an excellent opportunity for corporate counsel and compliance professionals to examine their policies regarding internal investigations and employee relations. In undertaking such a review, organizations should start with the following three fundamental policies.

The role of counsel in conducting internal investigations

As always, a critical component of corporate policy on internal investigations is whether and when counsel should direct the investigation. When the issues involved in an investigation are sufficiently serious, attorney involvement is, of course, necessary to protect appropriately the company's interests. DOJ's new policy on corporate cooperation provides additional assurances that, even when counsel directs an investigation, privileged communications likely will remain confidential. The policy does not, however, change the fact that revealing the conclusions of an attorney-led investigation might risk waiver of the privilege. Accordingly, corporations cannot simply assume that everything counsel does in an internal investigation will remain confidential and privileged. With the help of qualified counsel, corporations still must weigh these competing considerations and fashion counsel's role carefully.

When to discipline employees

Under the revised guidelines, the DOJ allows corporations more flexibility and discretion in employment matters arising from alleged illegal conduct. Corporate leadership may exercise discretion in determining whether to keep an individual employed until the government's investigation has been resolved or, instead, to terminate the employee immediately. Corporations also may steer a middle course and adopt policies that provide for paid or unpaid leave during the course of an investigation. When deciding how to discipline employees, though, a corporation must always remain cognizant that the reasonableness of its actions will continue to be a factor in the government's analysis of the

effectiveness of its compliance program.

Whether to indemnify and advance legal fees

Under the DOJ's new policy, a company may advance legal fees to employees in good faith without concern that the action will harm the company's ability to cooperate with the government. Under DOJ's prior policies, some companies had instituted bylaws providing for mandatory advancement of legal fees. Such policies were intended to avoid any accusation by DOJ that the choice to advance legal fees to any particular individual was an indication that the company was uncooperative. The downside to such a mandatory policy was that the corporation might find itself advancing legal fees to a malefactor who clearly should not receive the organization's support. Under DOJ's new policy, however, a corporation can retain the discretion to advance (or not advance) legal fees without risk of harming its standing with the government.

Conclusion

DOJ's revised policies on corporate cooperation provide a welcome change of direction for the government in its attempts to shape responsible conduct by organizations. These policies have always been based, at least in part, on a desire to cause corporations to police their own ranks and to assist the government in bringing individual law-breakers to justice. In the past, however, DOJ has often overstepped the bounds of wise policy and injured important legal protections, such as the attorney-client privilege and the constitutional right to counsel. Now that Deputy Attorney General Filip has brought DOJ policy more closely in line with these principles, corporations and their attorneys must reconsider how best to structure compliance programs and policies that likewise strike the proper balance between protecting the organization, treating employees fairly, and ensuring that the laws governing corporate conduct are followed appropriately. ■

1 No. 07-3042-cr, 2008 WL 3982104 (2d Cir. Aug. 28, 2008)
2 Memorandum from Eric H. Holder, Federal Prosecution of Corporations (June 16, 1999), available at http://www.usDOJ.gov/criminal/fraud/docs/reports/1999/chargingcorps.html.
3 See "Former Computer Associates Executives Indicted on Securities Fraud, Obstruction Charges" DOJ Press Release (Sept. 22, 2004) at http://www.usDOJ.gov/opa/pr/2004/September/04_crm_642.htm.
4 Memorandum from Larry D. Thompson, Principles of Federal Prosecution of Business Organizations (June 20, 2003), available at http://www.usDOJ.gov/dag/cftf/corporate_guidelines.htm.
5 Memorandum from Paul J. McNulty, Principles of Federal Prosecution of Business Organizations (December 12, 2006), available at http://www.usDOJ.gov/dag/speeches/2006/McNulty_memo.pdf.
6 Letter from American Bar Association to Attorney General Alberto Gonzales (May 12, 2006), available at http://www.scribd.com/doc/210828/Alberto-Gonzales-Files-American-Bar-Association-to-Gonzales-Letter.
7 See Justice Department Revises Charging Guidelines for Prosecuting Corporate Fraud (August 28, 2008), available at http://www.usDOJ.gov/opa/pr/2008/August/08_odag_757.html.
8 United States Attorney Manual, § 9-28.720.
9 See United States v. Stein, No. 07-3042-cr, 2008 WL 3982104, at *1 (2d Cir. Aug. 28, 2008).
10 See H.R. 3013—110th Congress (2007): Attorney-Client Privilege Protection Act of 2007, GovTrack.us (database of federal legislation), available at http://www.govtrack.us/congress/bill.xpd?bill=h110-3013.
11 Letter from Senator Arlen Spector to The Honorable Mark Filip (July 10, 2008), available at http://specter.senate.gov/public/index.cfm?FuseAction=NewsRoom.NewsReleases&ContentRecord_id=09ee0cfc-978b-d2cb-c6e6-511bec8ea4ea&Region_id=&Issue_id=&IsPrint=true.
12 See Senator Arlen Spector Press Release (August 28, 2008), available at http://specter.senate.gov/public/index.cfm?FuseAction=NewsRoom.NewsReleases&ContentRecord_id=0aa887f0-f40c-f557-5dbb-4aef8032b8f9.

Hope for Compliance? The personal dynamics of compliance work

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corrective action (or appropriate disciplinary action to a wrongdoer) gives people hope that someone really cares about fixing things and doing the job the right way. Discipline, fairly administered when things go wrong, gives people a sense that there is fair play in the organization, that there is "some justice in this world," even in the company they work for.

If we care, they will

All these elements of a compliance program work together to bring hope to the good employees of an organization. Remember—it is the majority of good employees who help the compliance program prevent the fraud and abuse committed by the few who are crooks.

But it is not just having a compliance program and implementing it; it is how you go about it. Sincerity, dedication that goes the extra mile, self-discipline on the part of management to ensure it listens to and respects its employees, providing resources to correct compliance problems—all work to help employees know that we are in this together to make things function right. By listening to employees' issues, working with their complaints, and advocating with management to solve the operational and systems challenges that are making the work difficult, a compliance program not only can give employees hope and courage, but can show them that the organization cares about them as people. It will help them to realize that they are worth something as individuals and are seen as more than just cogs in the wheels of healthcare. Buoyed by this sense of worth, they will truly care about their own jobs and enthusiastically want to do things the right way.

My German grandfather lived in the late 1800s and was a piano varnisher. His job was to carefully put layer upon layer of varnish on a finely built piano, sanding and polishing each layer until it shone. When it was finished, it was sold to a concert hall or put in the home of a wealthy person, where it was not only a well-made musical instrument, but also a thing of beauty. An effective compliance program should also be built like a fine piece of craftsmanship, and fine tuned to the needs of the organization. When you build this kind of life into a compliance program, it will succeed and endure. Employees will be proud of their work and will create an ethical culture on their own that will thrive and grow, which will last long after the compliance officer has left. Freedom: free choice, motivated by an inner desire – a hope – for something better, leaves a lasting effect. People will be changing, not because someone's asking tem to or looking over their shoulder, but because they want to. My goal as compliance manager is that, after I leave, the compliance program will continue to operate successfully for as long as the organization's people remember that there is always hope for compliance. ■

Bringing harmony from discord in hospital compliance

By Emilie Rayman, Esq. and Tom Jeffrey

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Compliance does not operate in a world of its own, even though many compliance officers seem to think so. There is a point of contact where Operations, Compliance, and Quality meet in a vortex of information that cannot be separated. To establish an appropriate meeting point, individuals responsible for each component need to understand the entire process, a process that touches upon patient care, Stark laws and Medicare rules, the Office of Inspector General (OIG) Work Plan, The Joint Commission standards, coding and billing, the Conditions of Admission, and Title 22.

If we look at the different hospital operations involved as musical divisions of an orchestra, such as the strings or horns, then Compliance might be likened to the percussion section, setting the beat for others to follow. The CEO would be the conductor, who could hear each distinct sound, choreograph the interplay, and mix the sound to produce the symphony, but be dependent upon each section. Therefore, the best approach to achieve harmony in compliance is one of collaboration and team work.

Unlike an orchestra, many hospitals will erect walls between each of the departments, either due to history or the territorial nature of the participants. You can imagine the sound of the symphony with partitions and people following conflicting rhythms. The sound, instead of being harmonious, is conflicted and noisy. It is imperative that the departments talk about issues and work together and that the compliance officer knows, or learns and understands, the compliance issues in each of the areas. It is easy to tune out issues about patient care or finance and coding and say that your world only pertains to CMS, OIG, HIPAA, and issues surrounding Stark and the anti-kickback regulations, but you would be covering less than a third of the compliance needs of your organization. OIG has added quality and patient care issues to its 2009 Work Plan and expects the compliance officer to be responsible for monitoring and reviewing these areas.

Compliance touches every department in a hospital and covers all processes in one way or another, so a good compliance officer should know the operations and business of the hospital and how they should function together. If you are one of those who don't know the operations and business side, the best advice is to follow patients from admission to discharge, spend a few days with Utilization Management/Review, spend another few days with Patient Billing, and still more days with Coding. These days do not have to be consecutive, but if you can take a little time out of each day, you will build your knowledge base. In addition, you should read The Joint Commission standards and process improvement goals and the National Safety Standards, spend a day with Utilization Management/Review and understand how the InterQual Criteria is used. Take a basic course in coding, so you understand levels of care and the coding rules. Most importantly, ask questions!

A brief explanation of the arrangement among Quality, Utilization Management/Review, Coding, Compliance, and other departments to work together at our hospital (CMHS), illustrates the importance of understanding how processes need to coordinate.

Quality Assurance is home for Core Measures, The Joint Commission standards, and National Patient Safety Goals. The regulations, which are process improvement standards, look at clinical processes and audit these processes through policies and procedures, education, and what The Joint Commission calls "tracers." During a randomly selected tracer, the auditor goes to a clinical practitioner and observes and interviews him/her about the process they are performing in order to verify whether they are following the correct process. An example of such a process is washing hands between each patient.

Root cause analysis is used when a problem is reported to find the cause of a problem. This is followed up with process improvement actions that typically include education. Core Measures and National Patient Safety Goals[1] (NPSG) are audited and generally lead to process improvement actions and education, such as the Core Measure for antibiotics within an hour of surgery to prevent infections, and the NPSG for checking the patient's armband to verify identification prior to giving medication.

Much of what Quality does is concurrent and looks at processes and ways to improve

them. Compliance, on the other hand, looks at what Quality has done and validates it retrospectively through an independent audit process as a second level of audit, if there is a problem. It is very important that Compliance understands what standards and goals Quality is trying to attain, in order to assist them and structure an audit coherently.

Root cause analysis is also used to investigate sentinel and "never" events. Often, connecting all of the dots between areas is missed unless there is constant monitoring by everyone. A good example of this is from an Institutional Review Board (IRB) that reviews serious adverse events (SAE) in connection with clinical trials. If the patient was in the hospital, Emergency department (ED), or one of the clinics, the event also needs to be reported to Quality and the appropriate government agency, if the incident is found to be a true sentinel or "never" event.

Continuous monitoring of the new Joint Commission standards is a huge undertaking and involves everyone at the hospital. In our health system, our Joint Commission monitoring teams are governed by Operation Readiness teams (Figure 1) and are further split into survey teams. The areas where Compliance directly crosses-over include the hotline reporting, investigations into violations of patient rights, failure to document and falsification of patient records, sentinel events, failure to report, and quality exceptions. Every vice president, the CEO, every director, and selected managers are assigned to survey teams, with the responsibility to monitor and survey Performance Improvement and Safety Goals. This is truly a team sport at CMHS.

Utilization Management/Review is involved in the day-to-day management of the patient, such as determining whether the patient

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Figure 1: The functional areas of coverage in continuous monitoring of the Joint Commission Standards

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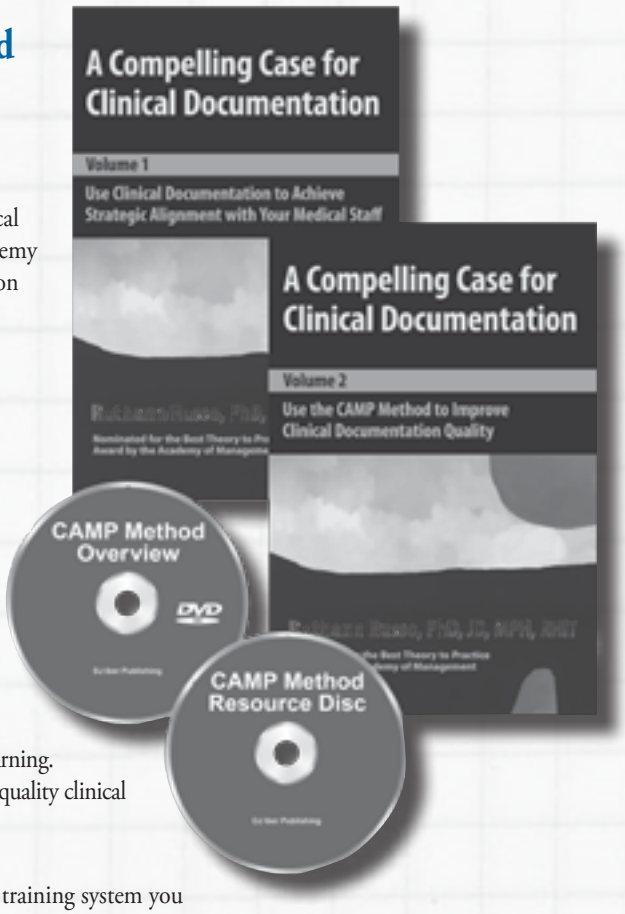

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needs a social service or dietary consult, speaking to the physician about moving the patient, arranging for discharge, taking care of the two-day notice to Medicare beneficiaries, and arranging for transfers to skilled nursing facilities (SNF).

Generally, Compliance is notified by Utilization Management if there is a problem that requires answers to an intervention. Audits in this area would include the two-day notifications to Medicare patients and whether the three-day stay prior to being transferred to a SNF was actually medically necessary. Audits of In-Patient to Out-Patient admissions are usually a combined Utilization Review and Compliance review. Utilization Management and Compliance are involved and responsible for putting together the appeals and Administrative Law Judge hearings for medical necessity denials for all payers, including Medicare and Medicaid.

Coding is part of Medical Records or Health Information Management (HIM), and is involved in ICD-9 coding of diagnoses and co-morbidities (secondary diagnoses), CPT-4 coding of procedures, diagnosis-related group (DRG) coding, ambulatory payment classification (APC) coding of out-patient visits (out-patient DRGs), and abstracting (i.e., a summary of the patient stay). Medical Records is also the official holder of all clinical records and is responsible for completeness of the file (e.g., making sure that the physicians have dictated and signed their history and physicals and discharge summaries). This is an area where every compliance officer should have a basic working knowledge of the coding that goes on in the institution. Coding is how a provider gets paid, and if coding is incorrect, it can lead to overpayment or underpayment, both of which are violations of the Medicare Conditions of Admission and which can, potentially, lead to a false claims charge.

Coding must be reviewed continuously and concurrently during the admission (at our hospital, it is performed by clinical coding specialists who also monitor Core Measures) and then reviewed retrospectively by Medical Records and audited by Internal Audit (conducted by independent auditors at CMHS).

Evaluation and management (E&M) coding is an out-patient and ED process, frequently referred to as the professional component of the bill. E&M coding first looks at whether the physician did a review of all the systems, discussed the chief complaint, evaluated the problem the patient was having, and reviewed the medications, family history, history of present illness and the patient risk, and medical decision making. The E&M codes correspond to level of care and payment. The ED nurses also select a level of care for payment, called the facility charge. If the professional component does not match the facility charge (i.e., the E&M code is a Level 2 and the facility charge is a Level 5), then the bill may be rejected. There may be a legitimate reason for the difference in coding, but Compliance is well-advised to investigate and review these mismatches for legitimacy (in our facility, the clinical coding specialists perform this function). Failure to review incorrect coding may result in a pattern to make the same mistake and continue to bill improperly for it. Generally, frequent, periodic audits of E&M coding are recommended to ferret out these types of errors and to make corrections, through education, before they become a problem.

Compliance audits become necessary when anyone in management becomes aware of a potential problem. How does Compliance know that there is a potential problem? Compliance officers have to be involved in the hospital business, go to Operations and Finance meetings, listen in ancillary meetings and Nursing, keep their ears open, and research what they don't understand. A compliance officer who stays behind closed doors and doesn't get involved in the business is a compliance officer in name only. Certain compliance internal audits that may expose the hospital to significant potential liability should be undertaken only under attorney-client privilege (with outside counsel). Audits performed under the Compliance department are otherwise discoverable, so you will want to consider putting some protections in place for your organization.

Finance and the Business Office are my favorite parts of the hospital. This is where it gets exciting as the medical records, coding, and the charges come together. The Charge Description Master (CDM), which has every chargeable item on it, and the Room and Bed Master, like a hotel room charge roster that covers room and board with nursing thrown in (a point of contention for most nurses) come into play as the bill is compiled and matched against what was coded and what was charged for, and the Medicare rules are applied. Once the billing is compiled, it is held for the final discharge diagnosis and final coding before being sent electronically for payment. Compliance audits may be for adherence to the Charity Care Policy, correct application of deductibles, and Medicare Secondary Payer Policies, to name just a few.

When Compliance thinks about "contracts," Stark laws, anti-kickback rules, and physicians usually come to mind. However, this is not the only understanding of contracts in a hospital setting. The majority of departments think of contracts in terms of services and supplies, and The Joint Commission views them as clinical contractors. Clinical contractors are those persons who provide patient care services to our patients and those contractors who are present in patient care

Continued on page 46

areas (e.g., equipment vendors demonstrating equipment in the Operating Room [OR]). Because these persons are involved in the care of our patients or near them, The Joint Commission says the facility must treat them as such and perform the same employee safeguards, such as drug testing, vaccination and inoculation record checks, OIG checks, and background checks. This area involves Human Resources, Medical Staff Office (MSO), Quality, and Compliance.

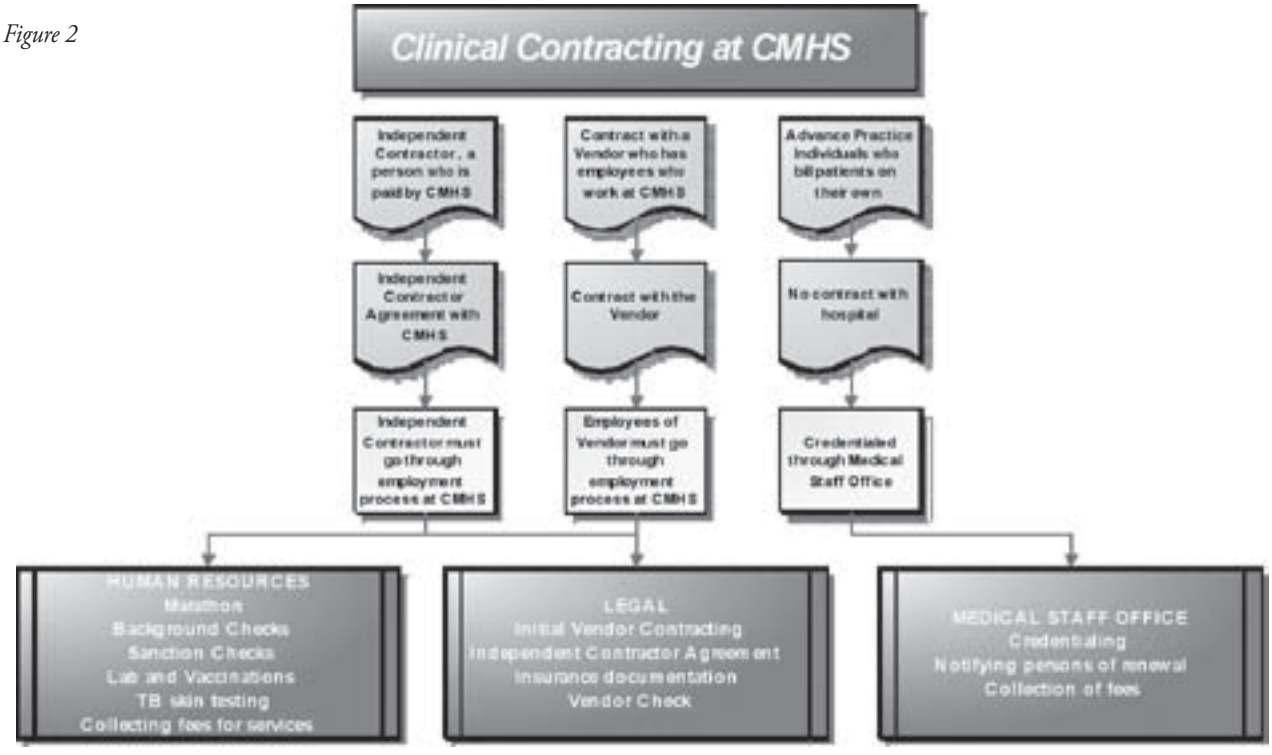
Because the question of who credentials whom is sometimes an issue, Figure 2 (below) illustrates how CMHS identifies which department credentials the contractors. Whenever a contract is submitted for clinical contractors, an addendum is attached for signature which outlines all the requirements for each of the employees (See Figure 3 on page 48). Once the contract is exercised, Compliance is responsible for the contract terms, such as insurance and renewal (e.g., MediTract). Human Resources and the Medical Staff Office are responsible for the credentialing (which are housed in VendorCheck and PreCheck). Quality is responsible for seeing that the competency requirement is met for the patient care areas, but in actuality, this is another example of coordination of all areas of the hospital.

Let me illustrate, through a hypothetical of a more granular vision, what actually happens at a hospital and point out the possible time bombs of data cross-overs ready to cause compliance road blocks in the absence of an effective team approach.

Our patient, Mr. Doe, comes into the ED at 2300 hours (11 p.m.) with a complaint of stomach pain after eating a five-course dinner. He stops at the registration window to check in. The clerk, if he or she is on the ball, refers the patient to the Triage Nurse for evaluation (before taking demographics or billing information, as is required by EMTALA under Disability, Housing, and Community Services [DHCS] and The Joint Commission). The patient is then evaluated by the Triage Nurse, who decides that Mr. Doe should be taken back to a bed to be seen immediately by the physician.

EMTALA is a regulation which is overseen by state and federal governments, and in most hospitals is covered by Nursing and the MSO. The regulation reaches deep into the business of running a hospital and governs hospital-to-hospital transfers, ED patient evaluations, coverage agreements, and physician on-call arrangements. Most Nursing and MSO departments do not have great tracking mechanisms for documenting on-call problems and blips in compliance. This is where the Compliance Office may be of assistance, with its reputation for employing great documenters and rat packers when it comes to keeping documentation. Also, in the area of self-reporting and the hotline complaints, Compliance is helpful, because it covers the documentation of these areas, too. Quality tracks the patient complaints, so I have found it helpful to give them access to the patient compliant portion of our hotline. Utilization and Quality Management are involved when

Figure 2



patient dumping allegations occur. Last, but not least, is Billing, which will hold that bill until all are assured that it was not the hospital that caused the problem. Regardless of whether or not the patient is to be admitted, the clinical staff needs to document what conditions were present on admission to the ED, along with the rest of the clinical assessment and what exactly was done for the patient.

Now we are ready to move on with our hypothetical patient. The physician evaluates Mr. Doe and writes orders. Now the clerk goes to the bedside to get information. Mr. Doe tells the clerk he is a Medicare beneficiary with group insurance from his spouse, which makes Medicare the secondary payer. Nevertheless, the clerk still needs to ask all the Medicare questions, such as: Is this related to a Black Lung Claim? Medicare data must be kept for 10 years, so it is important that the clerks get this right.

Mr. Doe is then asked to sign the Conditions of Admission and Advance Beneficiary Notice (ABN) if the physician orders tests that are not covered by Medicare. He is also given the hospital HIPAA guidelines and asked to sign an Acknowledgement of Receipt. Audits of whether the Conditions of Admission and ABN have actually been signed by the patient or his authorized representative should be done regularly. If the Conditions and ABN are not signed, the hospital cannot legally bill for the services provided.

Mr. Doe is subsequently discharged and sent home with After Care Instructions, a list of current medications (this is where medication reconciliation occurs, giving the patient a list of current medications, and this is tracked by Quality), and either instructed to see his private medical doctor or referred to a list of physicians to see within 24 hours (a Joint Commission requirement). The ED physician now codes the chart with an E&M code which corresponds to the level of care that was required by the patient, and the nursing staff codes the facility charges. So far, if we looked at auditing this patient, we would audit Medicare Secondary Payer Regulations, ABN signatures, E&M coding, and facility charges.

After he returned home, Mr. Doe tossed and turned all night, and goes to see his private physician in the morning. His physician decides that he needs to send Mr. Doe back to the hospital for a cholecystectomy, an out-patient procedure. The patient goes to the hospital, registers as an out-patient, and signs all the forms that he signed the night before. However, the clerk informs him that his ex-spouse dropped him from her plan and that he now only has his Medicare insurance. In the hospital, as preparatory work continues, the patient is prepped and a cholecystectomy is performed. However, the physician also found that Mr. Doe has a bowel obstruction. Mr. Doe is discharged as an out-patient and then admitted as an in-patient scheduled for surgery the following day for the obstruction. Mr. Doe comes through the surgery just fine and is discharged two days later. The bill is generated, but is stopped in coding because Mr. Doe was an out-patient who received an out-patient procedure. He was subsequently admitted for an "in-patient only" procedure and stayed in the hospital for three days; therefore, further review for billing is now necessary. Out-patient to in-patient changes after a patient has been discharged must be reviewed by the Utilization Review Committee, which consists of three doctors, two nurses, and a social worker. If they find that changing Mr. Doe to an in-patient is appropriate, they insert a late Utilization Review Summary in the patient chart, which explains their actions, and the billing is changed. If not, the billing stands and the hospital cannot bill Medicare for the in-patient surgery.

Is the hospital going to merge the original ED visit with the admission? Is the diagnosis the same? If yes, then the visits will merge; otherwise, no. If the hospital is doing a lot of in-patient to out-patient (or the reverse) reviews, an internal audit is in order. Quality is also checking for medication reconciliation on discharge and, if the patient received antibiotics at least one hour prior to surgery, Medical Records is checking for signatures and completion of history, physicals, progress notes, and OR reports. Utilization Review is checking the two-day rule.

Mr. Doe goes to the clinic for follow-up after his surgery and is seen by a nurse practitioner (NP). The patient is doing well and is sent home. Now, for billing, the NP bills under the physician's National Provider Identifier (NPI) at the clinic as "incident to" and reimbursement is at 100%.

However, if the physician is not there to supervise the "incident to," the NP must be certified by Medicare and have a registration with the clinic through Medicare to bill solo, and will only receive 85% reimbursement. Additionally, if Mr. Doe is a "new" patient or, in this case, has a "new" problem, he must be initially seen by the physician (under CMS rules), so under this hypothetical scenario this visit should not be billed. However, if this was just a follow-up visit for an existing problem, the clinic could bill for the NP. Note that some commercial payers do not recognize an NP billing on their own and, therefore, all billing for NPs is considered "incident to." Here, the clinical areas restructure their processes to make sure that all "new" patients and problems are seen by a physician, coding follows up as a second set of eyes, and finally, billing takes a third look at the patient records.

How do we all come together and coordinate all the activities? At CMHS, we are a closely-

Figure 3

ADDENDUM TO CONTRACT OF _____, Date:

"The (Party contracting with CMHS) shall agree that every (student, healthcare professional, contractor etc) participating in the (program or being hired as temp or traveler) at CMHS shall be subject to criminal background checks, alcohol/drug screening, and debarment and sanction checks for Federal and State Programs (Medicare/MediCal), and "Primary Source of Licensure" (if required for the person) prior to participating in clinical programs, performed by the (Contracting Party)."

"The (Party contracting with CMHS) additionally shall ensure that, prior to clinical placement, each person sent shall be skin tested for tuberculosis with a PPD test, provide documentation of required immunization as follows: Measles, Mumps, and Rubella (MMR): Tetnus/Diptheria booster; Chickenpox and Rubeola (2MMR)"

"The (Party contracting with CMHS) shall ensure that prior to clinical placement, each person has taken or declined the Hepatitis B series and has had instruction in occupational exposure to blood borne pathogens, protective practices to avoid contamination, and procedures for decontamination in case of exposure, or potential exposure to infections materials or potentially infectious materials."

"The (Party contracting with CMHS) agrees that all persons sent to CMHS for clinical practice reasons, shall sign and abide by the CMHS code of Conduct, and complete the CMHS Orientation Packet."

"CMHS has the right to audit, clinical practice, certifications, and clinical documentation of the contracting party periodically, throughout the life of the contract. ***Joint Commission Contracted Services Standard LD 3.50***"

Exhibit A (***Title 22, Section 70706***), shall be completed by the contractor for each person providing registration into Vendor Check by organization and then by each person.

EXHIBIT B

Resumes of all persons performing services at CMHS

Community Memorial Health System
147 North Brent Street
Ventura, CA 93003

Date:_____

Print Name_____

Signature_____

Other Parties info

Date:_____

Print Name:_____

Signature:_____

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knitted team with open doors, who meet at least weekly, if not more frequently. We call each other, e-mail, and generally, if there is a problem in the system, it belongs to all of us – not just one area. So, in my opinion, it is our approach to problem-solving and the general belief that we have an open architecture for communication which creates our good team work and an environment of cooperation.

This was only a very, very brief summary of how Compliance works with Quality and clinical areas at our health system. The reason we work so well together, without walls and turf battles, can only be attributed to our CEO, Gary Wilde, a visionary who leads by example and transparency. I have been at many other institutions, but this one truly has one goal and works together to achieve it. I believe that to get to the next level, Compliance has to be "one" with the institution. It is imperative for all compliance officers to educate themselves on the business of their institution, billing, coding, and clinical, including the quality initiatives and The Joint Commission standards, to succeed. ■

Special thanks to Summer Flores, JT Coordinator at CMHS for creating figure 1

1 The NPSGs are part of the patient safety trilogy espoused by the Joint Commission, which includes the Sentinel Event Standards and Guidelines, Patient Safety Standards, and the NPSGs.

Be Sure to Get Your CHC CEUs

Inserted in this issue of **Compliance Today** is a quiz related to the articles:

- **Creating effective company-wide compliance training: Knowledge, awareness and comprehension** — By Audrey Brahamsha, page 26
- **Feature focus: DOJ changes its rules for assessing corporate cooperation** — By R. Christopher Cook and Joseph W. Clark, page 30
- **Bringing harmony from discord in hospital compliance** — By Emilie Rayman and Tom Jeffrey, page 42

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Compliance Today readers taking the CEU quiz have ONE YEAR from the published date of the CEU article to submit their completed quiz.

The 2008 revised PhRMA Code: Interactions with health care professionals in the age of compliance

By Howard L. Dorfman

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The interaction between pharmaceutical manufacturers and health care professionals has come under increased scrutiny for some period of time. Most of the attention has taken a decidedly negative view of those interactions, with criticism regarding the adverse impact on the integrity of therapeutic decision-making coming from such entities as Congress, the Office of Inspector General of the Department of Health and Human Services (OIG), the Department of Justice, state attorneys general, and from leaders of academic medicine.[1]

In 2002, the Pharmaceutical Research and Manufacturers of America (PhRMA), the trade organization that represents research-based pharmaceutical and biotechnology companies, introduced the PhRMA Code on Interactions with Healthcare Professionals (PhRMA 2002 Code) in response to the criticism of industry marketing practices. As stated on the PhRMA website (www.phrma.org), the purpose of the Code was to reinforce the appropriate nature of the interaction with health care professionals as

> "…professional exchanges designed to benefit patients and to enhance the practice of medicine. The Code is based on the principle that a health care professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the health care professional's medical knowledge and experience."

Yet, notwithstanding the issuance of the various codes that address ethical standards in interactions with health care practitioners, criticism of industry conduct as creating an environment in which excesses impacted the health care professional's clinical judgment continued. In response, PhRMA issued a revised Code on Interactions with Healthcare Practitioners in July 2008 (PhRMA 2008 Code)[2] scheduled to take effect in January 2009. Although the original PhRMA 2002 Code represented a significant shift in pharmaceutical industry marketing practices and ended what had been viewed as some of the more egregious sales and marketing excesses, the PhRMA 2008 revisions have been described as more narrowly constructed and represent a targeted guidance in response to specific criticisms. The revisions generally reflect current industry "best practices" and take into account many of the government-imposed changes in marketing processes that have marked an evolution in the compliance environment since 2002.

The following section highlights the most significant provisions of the PhRMA 2008 Code, particularly where changes have been made to the PhRMA 2002 Code.

Informational presentations and meals

A standard method by which pharmaceutical company sales representatives would interact with health care professionals to facilitate an informational presentation has historically been through providing a meal. The PhRMA 2002 Code permitted manufacturers to offer health care professionals the occasional modest meal solely to facilitate that presentation or discussion with industry representatives and others speaking on behalf of the company, and only where the venue is conducive to informational communication. There was no other limitation as to location.

The revised PhRMA 2008 Code allows the modest meal while making a scientific or clinical information presentation to health care professionals and their staff. However, that modest and occasional meal "offered in connection with presentations made by field sales representatives or their immediate managers should …be limited to in-office or in-hospital settings."[3] The revised PhRMA 2008 Code does not eliminate the out-of-office or out-of-hospital meal entirely as a means of facilitating a speaker program.

It is important to read the remainder of the revised PhRMA 2008 Code and the accompanying questions and answers (Q&As) for greater clarification regarding distinctions among the types of pharmaceutical employees in the context of permitted or prohibited

activities. For example, Question 12 indicates that if the pharmaceutical company personnel who are hosting a business discussion are home-office based and not field sales, an out-of-office or hospital setting for the meal is permitted.[4] The Q&A does not specifically address non-sales field personnel (such as medical science liaisons or similar field-based medical staff) which, presumably, would be permitted to provide out-of-office meals. By refusing to utilize the more expansive descriptive language used in other sections of the PhRMA 2008 Code, such as "company representatives" or "industry representatives" or "all company representatives who visit health care professionals," it is reasonable to conclude that the drafters created certain distinctions as to appropriate conduct based on the company roles played by pharmaceutical manufacturer personnel.

Prohibition on entertainment and recreation

The PhRMA 2002 Code permitted entertainment in the context of consultant meetings or speaker training sessions provided such entertainment and recreation were clearly subordinate both in time and emphasis to the business agenda of the meeting. The PhRMA 2008 Code eliminates entertainment entirely in these contexts. For the first time, companies are prohibited from providing entertainment or recreation in any interactions with health care professionals. The prohibition applies regardless of the relative value of the activity or whether it is secondary to the consultant or educational purpose of the meeting.

Support for Continuing Medical Education

The importance of defining the appropriate role for the pharmaceutical industry in relation to support for Continuing Medical Education (CME) is reflected in the PhRMA 2008 Code. Unlike the PhRMA 2002 Code, the CME section is now independent of other code provisions. New requirements are consistent with several of the recommendations found in the OIG Compliance Guidelines for Pharmaceutical Manufacturers[5] and reflect guidelines issued by the Accreditation Council for Continuing Medical Education (ACCME).[6]

The CME provisions track the general philosophy found throughout the PhRMA 2008 Code in stressing the need for the industry to distance the sales and marketing functions from purely educational endeavors critical to the independence of developers of CME materials. As the PhRMA 2008 Code suggests, support for CME is intended to educate health care professionals on a full range of treatment options, not as a means of promoting a particular therapeutic option. To accomplish this goal, pharmaceutical companies are to separate the CME grant review process from the involvement of sales and marketing personnel and to follow ACCME or other accrediting entity standards. Companies are no longer permitted (as they were under the PhRMA 2002 Code) to provide meals or receptions directly at CME events. Instead, they are required to provide funding to the CME provider for meals for all attendees.

A significant change relates to the ability of a pharmaceutical manufacturer to provide guidance to the CME provider in the development of the CME programs. The PhRMA 2008 Code states that manufacturers are no longer permitted to provide guidance regarding potential speakers or content, even if an unsolicited request is received from the CME provider. These guidelines, which speak of near absolute separation between industry and CME providers, would likewise suggest that the practice of allowing company medical personnel to review CME materials in advance for factual accuracy is now highly suspect. However, it appears that a company may establish a Request for Proposals concept as part of the decision-making process regarding which CME areas to fund (See PhRMA 2008 Code, Q. 21).[7]

Consultants

This section of the PhRMA 2008 Code begins by reiterating the general principles stated in the PhRMA 2002 iteration and enunciates the very basic standards for establishment of consulting arrangements between manufacturers and health care professionals and lists factors that support the existence of bona fide consultant engagements. A justification is now included, that "the use of expert advice to ensure that…medicines are meeting the needs of the patients," which reprises a consistent theme relating to patient interests that is stressed throughout the revised code. The PhRMA 2008 Code also contains several additional details regarding the consultant arrangement, such as the need for a written contract and for the need for the services to be provided. The company should likewise be prepared to justify the need for the number of consultants being retained.

The PhRMA 2008 Code expands on the criteria to be utilized in the selection of consultants and states that the decision regarding the selection or retention of health care professionals as consultants should be based on "defined criteria," such as general medical expertise and reputation, and paid based on an undefined "fair market value." The PhRMA 2008 Code also expressly states that resorts are inappropriate venues for consultant meetings.

Although unstated, the PhRMA 2008 Code suggests new responsibilities for the pharmaceutical manufacturers regarding the use of consultants, apart from the now common

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concern regarding appropriate recompense and venues. The language as to "selection or retention" in the Code suggests a need to monitor consultants and document the extent to which their services will be required beyond the term fixed by contract. As will be discussed further, the need to maintain records of payments to consultant health care professionals is not only implicitly suggested by the PhRMA 2008 Code, but required by an increasing number of states.

Speaker programs and speaker training meetings

The concept of the speaker bureau (i.e., the retention and training of health care providers to speak at various venues on behalf of a pharmaceutical company's products within label) has come under scrutiny and criticism from various sources for a wide range of reasons. Concerns include excessive payments made to the speakers as a reward for past prescribing activity or as an inducement for future prescribing (a possible violation of the Anti-Kickback statute) and as a means of disseminating off-label information under the guise of an in-label presentation (a possible violation of the Federal False Claims Act and the Federal Food, Drug and Cosmetic Act). Although the PhRMA 2008 Code retains the concept of the health care professional as paid speaker, speaker programs are afforded separate discussion from consultant activities, and new restrictions are imposed that will require careful review of existing internal policies and procedures.

The revisions found in the PhRMA 2008 Code incorporate additional compliance concepts regarding the retaining and training of speakers who have become ubiquitous in most company compliance programs since the release of the PhRMA 2002 Code and reflect the OIG Guidance as well as a number of Corporate Integrity Agreements (CIA). The Code confirms that speaker programs are promotional in nature and that companies should take care to establish a distinction between such engagements and CME activities. To assist in clarifying the distinction, the Code repeats a number of the requirements suggested for consultant engagements, including:

- prohibiting speaker programs from being held at resorts,
- requiring a written contract that includes fair and reasonable compensation based on FMV,
- establishing a need for the speaker's services, and
- establishing the relevant expertise of the speaker.

A number of additional requirements are included. By way of example, and specifically responding to the concerns raised, the PhRMA 2008 Code enunciates a clarification that any health care professional engaged to undertake external promotional activities is deemed a speaker who should clearly identify that he/she is speaking on behalf of the manufacturer and that the information he/she presents is consistent with current labeling and applicable FDA guidance.

In addition to the responsibilities on the speakers, new requirements are imposed on the retaining companies, several of which will no doubt require a careful review of existing compliance policies and procedures. Pharmaceutical manufacturers must develop and implement policies that address the appropriate use of speakers and establish the appropriate number of speaking engagements for any particular speaker over time. Speakers are to undergo training regarding the company's products to understand the approved product labeling as well as FDA regulatory requirements. (These training sessions are not to be held in resorts.)

Of particular note are two new requirements. The pharmaceutical company is responsible for the active monitoring of its speaker programs to verify compliance with all applicable FDA regulations. In addition, each manufacturer is required to "cap the total amount of annual compensation it will pay to an individual health care professional in connection with all speaking engagements." No fixed cap amount is provided by the PhRMA 2008 Code, leaving the decision regarding establishing a reasonable limit to the judgment of the company. However, timely access to the pertinent information throughout the organization to permit an accurate assessment of compensation paid to any particular speaker may provide challenges for some companies.

Prohibition of non-educational items

The PhRMA 2008 Code effectively eliminates the category of "practice-related gifts" of nominal value imprinted with the company's name or logo as appropriate for distribution to health care professionals and their staffs. This includes such classic give-away items as pens, mugs, notepads, or other such reminder pieces. Instead, and in keeping with the stated objective of establishing the industry–health care practitioner relationship as based on education to the physician and benefit to the patient, the PhRMA 2008 Code redefines "educational items" which are permissible as "items designed primarily for the education of patients or health care professionals, if they are not of substantial value ($100 or less) and do not have value to the health care professional outside of his or her professional responsibilities."[8] Even permissible items, however, must be offered only on an occasional basis and be permitted by law. As pens and mugs and similar pieces do not "advance disease or treatment education," they are banished from the marketing armamentarium.

These newly articulated restrictions do not appear to require that a gift provided to a health care professional have no independent value, only that the item have no independent value to the health care professional outside of the professional's practice. Similarly, it does not appear that the prohibition on "practice-related items" means that an educational item cannot have value to the health care professional's practice. That interpretation runs counter to other sections of the PhRMA 2008 Code (See, for example, PhRMA 2008 Code Section 11). As a result, items that have value in relation to a medical practice, such as an anatomical model or a patient tracking form, are clearly permissible and specifically addressed in the PhRMA 2008 Code as educational items with no value to the health care practitioner outside of the practice and do not represent prohibited "practice-related items."

Prescriber data

Another example of how the PhRMA 2008 Code addresses a criticism of the pharmaceutical industry can be seen in the new section pertaining to the access by companies of data relating to prescribing activities by health care professionals. Criticism of access to and use of health care practitioner prescribing data by pharmaceutical companies, particularly by their field-based sales force, had grown since the PhRMA 2002 Code was released. In the PhRMA 2008 Code, companies were advised to use non-patient identifiable prescribing data responsibly. The Code further requires the development of company policies regarding the appropriate use of such data. Companies are further urged to respect and abide by the wishes of any health care professional who requests an opportunity to opt-out of any process that provides his or her data to sales representatives,[9] to educate company "employees and agents" regarding company policies, and to establish disciplinary procedures for misuse of such data.

Training and conduct of field representatives

Throughout the PhRMA 2008 Code, the interactions between health care professionals and pharmaceutical company personnel, particularly the field-based sales representatives, are to be based on informing the medical professional about medical and scientific issues where only the "highest ethical standards" are to be followed. To further reinforce this concept, companies are required to ensure that all company representatives who visit health care professionals (i.e., beyond field-based sales representatives) receive training on the applicable laws, FDA regulations, and industry codes of practice (i.e., the PhRMA Code) as well as training on general scientific and product-specific information. More importantly, companies are to assess their representatives periodically to determine that they comply with relevant company policies and to take appropriate disciplinary action when representatives fail to comply.

Field-based sales representatives will have ample opportunity to utilize the training they receive. Presumably, it will be the responsibility of these representatives to monitor speaker programs to establish compliance with the requirements of discussing current, on-label promotional information. The importance of this function should not be underestimated (particularly given the focus of such entities as the FDA, OIG, the Department of Justice, and the various state attorneys general in investigating off-label promotion for future prosecution) on both the state and federal level.

Formulary committee members

If the PhRMA 2008 Code can be viewed as a response to criticism of the industry that has continued since the PhRMA 2002 Code, as well as articulating guidance in light of various investigations and resultant CIAs, an example can be seen in the newly introduced section on the need for corporate disclosure relative to interactions with formulary committee members.

Although the PhRMA 2002 Code is silent regarding the issue of disclosure of relationships between health care professionals and the industry, the PhRMA 2008 Code states that companies should require health care professionals who consult or speak for industry and who sit on formulary committees to disclose the existence and nature of their relationship with the company. In this regard, the disclosure requirements should extend for a minimum of two years following the termination of the relationship with the company. However, only if the formulary committee procedures require it would the company-retained member recuse themselves from decisions that the committee makes regarding a medicine for which they speak or consult.

Implementing and adhering to the Code

The PhRMA 2008 Code, like its predecessor, is an articulation of guidance, and antitrust principles prevent an association such as PhRMA from dictating internal policies to its members. Yet, to address the criticisms of the industry, as well as to take into account the conduct that gave rise to the several investigations, settlements and CIAs since 2002, the PhRMA 2008 Code anticipates a certification process for companies that commit to implement its provisions. Compliant companies would post a company "certification" that policies and processes are in place to foster Code compliance.

Further, companies will be encouraged to seek external verification at least once every three years that they, in fact, have such policies and processes in place.

Conclusion

The implications of the PhRMA 2008 Code for the US pharmaceutical industry are

Continued on page 60

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Los Angeles, CA ..... **June 26**

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significant. It is critical for the individual companies to review their existing policies and procedures to determine if they meet the new requirements suggested by the revised Code. Even those entities currently operating under a CIA, Deferred Prosecution Agreement, or other compliance-related obligations, would need to determine the extent to which the PhRMA 2008 Code requires additional processes, such as external verification, in addition to those already in place. Moreover, PhRMA has indicated that it will direct any complaints about inappropriate corporate conduct to that company's Chief Compliance Officer (CCO) and will identify on its website those companies that have obtained external verification of its policies and procedures to foster compliance. In addition, several states and the District of Columbia have already passed legislation governing interactions with health care professionals. That legislation establishes the PhRMA 2008 Code as an important basis for determining appropriate industry conduct and possibly expands the grounds for criminal and civil liability for companies and their executives.[10] It is safe to state that compliance has become a complex and ongoing issue for the pharmaceutical industry that will continue to dominate the industry's already crowded agenda for years to come. ■

The author gratefully acknowledges the assistance of Ann Lewis, Counsel at Ropes & Gray.

1 References Troyen A. Brennan, et al., 'Health Industry Practices That Create Conflicts of Interest," JAMA 295 (2006): 429
2 PhRMA 2008 Code, www.phrma.org/files/PhRMA%20Marketing%20Code%202008pdf
3 PhRMA 2008 Code at 4
4 PhRMA 2008 Code at 23
5 OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 2003 (http://www.oig.hhs.gov/authorities/docs/o3/050503FRCPGPharmac.pdf)
6 Accreditation Council for Continuing Medical Education, http://www.accme.org/
7 PhRMA 2008 Code at 29
8 PhRMA 2008 Code at 12
9 PhRMA 2008 Code at 13
10 See, for example, Massachusetts Senate Bill 2863, An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care, available at http://www.mass.gov/legis/bills/senate/185/st02/st02863.htm

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Inserted in this issue of **Compliance Today** is a quiz related to the articles:

- **Creating effective company-wide compliance training: Knowledge, awareness and comprehension** — By Audrey Brahamsha, page 26
- **Feature focus: DOJ changes its rules for assessing corporate cooperation** — By R. Christopher Cook and Joseph W. Clark, page 30
- **Bringing harmony from discord in hospital compliance** — By Emilie Rayman and Tom Jeffrey, page 42

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Compliance Today readers taking the CEU quiz have ONE YEAR from the published date of the CEU article to submit their completed quiz.

ASK LEADERSHIP

John asks the leadership your questions

Editor's note: John Falcetano is Chief Audit/ Compliance Officer for University Health Systems of Eastern Carolina and a long-time member of HCCA. This column has been created to give members the opportunity to submit their questions by e-mail to jfalcetano@suddenlink.net and have John contact members of HCCA leadership for their response.

QUESTION:
Is an outlier payment affected if a hospital offers a discount to non-Medicare patients who are uninsured?

Answer provided by John C. Falcetano, MA, CHC, CIA
Chief Audit & Compliance Officer
University Health Systems of Eastern Carolina
Greenville, NC

A similar question was asked of CMS and their response was as follows:

When a hospital discounts charges to non-Medicare patients, such as uninsured patients, there is no effect on outlier payments under either Medicare's Hospital Inpatient Prospective Payment System (IPPS) or Medicare's Hospital Outpatient Prospective Payment System (OPPS). Only Medicare reimbursable cost and the undiscounted Medicare covered charges from the Medicare claims are used to calculate the cost-to-charge ratio.

The cost-to-charge ratio is applied to the undiscounted Medicare covered charges from each Medicare claim to calculate the outlier threshold and the outlier payment. Similarly, to the extent that other payments (including new technology add-on payments) under the Medicare program are derived by use of a cost-to-charge ratio, the cost-to-charge ratio is applied to the undiscounted Medicare covered charges to calculate the Medicare payment amount. ■

New HCCA Members

The Health Care Compliance Association welcomes the following new members and organizations. Please update any contact information using the Member Center on the Web site, or e-mail Karrie Hakenson (karrie.hakenson@hcca-info.org) with changes or corrections.

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- Misty Channell, Corporate Compliance, HealthSouth Corporation
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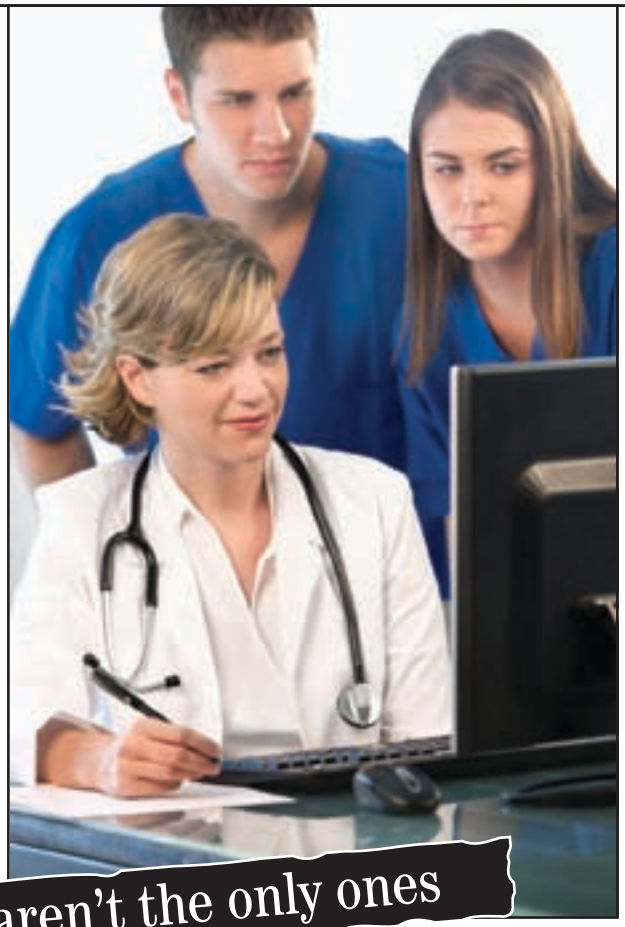

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