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Evaluating your medical necessity compliance and admission review program

By Ralph Wuebker, MD, MBA

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In an ever-changing health care compliance environment, it is imperative that hospitals establish a strong compliance program and evaluate it regularly to identify areas of strength and areas for improvement. The best way to defend against inappropriate denials is to ensure a compliant daily process for review and certification of medical necessity for every patient who enters the hospital.

The following nine questions will assist hospitals in evaluating their current medical necessity admission review program.

1. Does the utilization review (UR) plan reflect a compliant process, and is it consistent with the UR standards as outlined in the Medicare Conditions of Participation (CoP)?
The Centers for Medicare & Medicaid Services (CMS) have put forth regulatory guidance for the creation of a UR Committee. The UR Committee is mandatory and charged with the task of creating and evaluating the UR plan. The Medicare CoP[1] states the hospital must have in effect a UR plan that provides for review of services furnished by the institution and by members of the medical staff to patients entitled to benefits under the Medicare and Medicaid programs.

2. Does case/utilization management follow a process of strict application of screening criteria for all Medicare beneficiaries?
The first-level review of a case is typically conducted using industry standard screening criteria, such as Milliman® or Interqual®. If a definitive medical necessity determination cannot be made after applying the first level of screening criteria, the case needs to then go through a second-level review completed by an expert Physician Advisor.

3. Is case/utilization management using the most updated version of UR screening criteria?
It is important that UR staff use the most updated version of UR screening criteria, because medical necessity rules and guidance are constantly evolving and screening criteria change along with standards of care.

4. Is the medical necessity admission review process in effect seven days per week, 365 days per year?
A hospital cannot have a fully compliant medical necessity review process only 40 hours a week. Patients are admitted to the hospital every hour of every single day and your medical necessity admission review process needs to reflect this.

5. Is there ongoing training and education available for case/utilization management? Do the Physician Advisors remain up-to-date on ongoing regulatory guidance changes and the latest evidence-based care guidelines and outcomes?
Because the medical necessity field is constantly updating and changing, ongoing education of UR staff is necessary to ensure continued compliant practices. It is important that Physician Advisors

are abreast of any changes in regulatory guidance set forth by National Coverage Determination (NCD) and Local Coverage Determination (LCD) guidelines as they become available.

6. Are there processes in place to ensure ongoing communication among case management, Physician Advisors, and treating physicians?
There is not one group that is more important than the other in making a compliant medical necessity determination. Treating physicians, Physician Advisors, and case management need to work together as one unit to ensure a clinically and regulatory appropriate verification of medical necessity; that is, appropriate care in the appropriate setting.

7. Does the UR process ensure the creation of an enduring and auditable document that provides permanent evidence of your UR process for each Medicare case?
Each determination needs to be accurate, compliant, and most importantly, defensible. The reasons for the determination are as important as the determination itself. If the document is audited, there needs to be enough substance to defend the determination, and concordant documentation by the treating physician needs to be in the medical record.

8. Are the treating physicians at the hospital educated regularly on the importance of complete documentation, the need to work closely with case/utilization management and Physician Advisors, and their responsibility in ensuring both hospital and physician regulatory compliance?
Treating physicians have been identified as an area of focus and they will be held accountable for their determinations by Medicare Administrative Contractors. First Coast Service Options Inc.'s (FCSO) Program Integrity and Provider Outreach and Education Departments state

> effective Jan. 1, 2012, FCSO also will perform post-payment review of the admitting physician's and/or surgeon's (Medicare) Part B services related to inpatient admissions that are denied either because they do not meet the level of care criteria, as services performed could have been performed in a less intensive setting (i.e., outpatient) or documentation did not support the medical necessity of the procedure.

9. Is a regular analysis of the hospital's Program for Evaluating Payment Patterns Electronic Report (PEPPER) and other benchmarking data completed to look critically at observation and one-day stay rates to identify areas that need improvement or more attention?
A hospital's PEPPER compares observation and admission rates for certain diagnoses and procedures across similar hospitals. Hospitals can identify areas for improvement by identifying and analyzing areas where their inpatient/observation rates are significantly higher or lower than the other hospitals in their category, and the rates are not otherwise explainable.

Summary

Evaluating your medical necessity compliance and admission review program and providing ongoing education are key elements in keeping all parties involved in the UR Committee compliant and up-to-date on all regulations. ■

1. Title 42 of the Code of Federal Regulations, section 482.30 (42 C.F.R. § 482.30)

Promoting commercial reasonableness in hospital-physician relationships

By: Christopher G. Fete, JD, MHA; Drew Hoffman; and Daniel P. Stech, MBA, CMPE

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The standard of fair market value (FMV) has been the principal consideration for compliance personnel when contemplating payments from a hospital to a physician. Recently, there has been a surge of compliance concern surrounding the additional standard of commercial reasonableness that is found in most of the exceptions to the Stark Law and Anti-kickback Statute's safe harbors. The rising concern can be attributed to a series of government enforcement actions that have focused on the commercial reasonableness of the subject compensation arrangements. This article provides additional information on commercial reasonableness and practical steps that may be taken to help promote compliance processes and documentation in connection with hospital-physician transactions.

The industry concern was sparked by recent lawsuits brought by whistleblowers against several health systems. Two cases that the health care industry is keeping a close eye on are *U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, and *U.S. ex rel Baklid–Kunz v. Halifax Hospital Medical Center*.[1] Both of these cases involve the enforcement of fair market value and commercial reasonableness as the primary focus for the government/*qui tam* action.

The *Tuomey* case lawsuit was brought by a physician against Tuomey Healthcare System. The physician accused Tuomey for violations of the health care fraud and abuse laws and the Stark Law regarding part-time employment agreements with local physicians. The government contends that Tuomey entered into part-time agreements with 19 physicians that violated the Stark Law because the compensation arrangements were allegedly in excess of fair market value, were not commercially reasonable, and took into account the value or volume of physician referrals to Tuomey.

The alleged violations arose when Tuomey decided to enter into the described part-time employment contracts with a variety of surgical subspecialists in response to the emergence of a new surgery center in the local market. The allegations stated that Tuomey entered into the arrangements to prevent physicians who performed large volumes of surgical procedures at Tuomey from performing procedures at the new facility.

The contracts in question were 10 years in length and required that the employed physicians exclusively perform outpatient surgery at Tuomey's outpatient surgery center. The physicians were not required to work a designated number of hours under the contracts and were able to continue operating their private practices, but were paid as full-time employees of Tuomey. Under the arrangements, the physicians were paid for all professional services associated with procedures they ordered at Tuomey as

well as for the surgeries performed on site. After analyzing the agreement, a jury agreed in part with the government, and the court found that Tuomey was liable under the Stark Law. However, there was no finding that Tuomey violated the False Claims Act.

The *Halifax* case is a whistleblower lawsuit brought by Halifax's own Director of Physician Services. The government joined the lawsuit because they believe the financial arrangements between Halifax and some of its doctors violate the Stark Law and the federal Anti-kickback Statute. Specifically, the government alleges that the arrangements with these physicians were improper because the payments were above fair market value, were not commercially reasonable, and/or they took into consideration the volume or value of referrals.

Neither of the cases mentioned above has issued a formal opinion. In *Tuomey*, the government has appealed the decision and the verdict is still waiting to be heard. The *Halifax* case is still in the infancy stage and waiting to be decided. Because a written opinion is currently unavailable for either case, many health professionals, including attorneys, are stuck in a state of limbo with regard to the ultimate implications of the case. Most of the discussions coming out of the *Tuomey* decision have centered on the government's position on the commercial reasonableness of employment and other arrangements with physicians and the industry's reliance on legal and valuation consulting opinions. Nonetheless, *Tuomey, Halifax*, and other ensuing decisions have sparked the recent influx of debate surrounding the analysis of Stark Law violations.

In *U.S. v. Campbell*,[2] the court held that an employment arrangement between the University of Medicine and Dentistry of New Jersey and several cardiologists was completely commercially unreasonable. The government in this case attacked the arrangement from a business perspective and also argued that the physician (Dr. Campbell) was not qualified to teach at the school and that there were no efforts made by the University to ensure that the cardiologist was actually performing the teaching services.

In *U.S. ex rel. Singh v. Bradford Regional Medical Center*,[3] the court issued summary judgment against a hospital, a physician practice, and its physician owners, finding that an equipment subleasing arrangement and a related non-compete agreement improperly assigned value to the volume of "anticipated referrals" in violation of the Stark law.

Issues related to the commercial reasonableness standard

As mentioned above, several of the exceptions and safe harbors under the Stark Law and the federal Anti-kickback Statute require that the personal service agreements between physicians and health care entities be commercially reasonable. Despite references in these highlighted sections, neither the Stark Law nor the federal Anti-kickback Statute provides any clear guidelines to assist health care entities in their compliance efforts. The only guidance appears in the Centers for Medicare & Medicaid Services (CMS) commentary to the federal regulations.

CMS is the only government entity that has published a definition for commercial reasonableness. CMS's commentary has defined commercial reasonableness as an arrangement that appears to be a sensible, prudent business agreement, from the perspective of the parties involved, even in the absence of any potential referrals.[4] Furthermore, CMS has stated that

> an arrangement will be considered 'commercially reasonable' in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable

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> entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS [Designated Health Services] referrals.[5]

The definition given by CMS does not provide an objective, definitive standard for health care entities to apply in their compliance efforts. As a result, these entities and their advisors are left without clarity and are developing systems to maintain compliance with these complex laws. In response to the outcome of the *Tuomey* case, The American Hospital Association (AHA) filed an amicus brief [6] in support of Tuomey Healthcare. AHA explained that the Stark Law is extremely complicated and has forced many hospitals to rely on clarifying statements and explanations that CMS publishes with the regulations. The AHA further contends that the lack of clarity surrounding these issues makes compliance with the laws extremely difficult. Therefore, hospitals and health care entities are forced to rely on CMS's published commentary to assist in their compliance efforts.

Analyzing commercial reasonableness

The recent line of cases that has come down has brought the issue of defining commercial reasonableness to light and has motivated health care providers to search for answers. The outcomes of these cases have demonstrated that commercial reasonableness must be a separate analysis that should be employed in parallel to, or even in advance of, a FMV analysis.

It is important to recognize that while remuneration in a transaction can be determined to be within FMV, the arrangement can still fail the commercial reasonableness test. In light of the recent government enforcement actions regarding violations of the Stark Laws and Anti-kickback Statute, it is important to acknowledge this regulatory consideration when entering into financial relationships with health care professionals. Specifically, the parties should identify and document specific factors that promote the commercial reasonableness of the arrangements that arise in the health care sector.

Despite the fact that there is no clear definition provided in the federal regulations, there has been some guidance provided as a result of case law. One place to look is the government's expert testimony.[7] This testimony can be used as a platform for determining relevant issues to consider when analyzing commercial reasonableness.

From a practical standpoint, commercial reasonableness is the composition of conditions that provide the business rationale for entering into particular arrangements. Therefore, commercial reasonableness can be gleaned from a progression of questions and responses based on the transaction details. From a hospital's perspective, relevant questions to consider when analyzing commercial reasonableness include:

1. What is the hospital's specific purpose for contracting for the services or conducting the transaction?
2. Does the arrangement meet the need/demand for the services of the hospital and surrounding community? Is there any objective data available that indicates a hospital and community need for these specific services?
3. Absent patient referrals, what benefits do the hospital and community receive from the arrangement?
4. Does entering into the arrangement solve or prevent an identified business problem for the hospital?
5. Are the terms of the arrangement sensible and consistent with accepted business practices? Factors to consider include: duration, renewal, termination, compensation review, and other relevant contractual terms.
6. Is the arrangement explainable? In other words, on its face, is the arrangement clear and are the tasks, duties, and

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responsibility expectations clearly articulated and documented?
7. Absent patient referrals, does the agreement make economic sense for both parties?
8. Is the arrangement consistent with other arrangements of similar nature observed in the industry?

Additional factors may need to be considered when evaluating medical directorship arrangements. Such factors to consider include, but are not limited to:

1. Is the scope of the directorship duties reasonable and consistent with other comparable directorships in the industry?
2. Is there thorough documentation of administrative and clinical responsibilities (percentage of time and amount of time expended for each)?
3. Are there internal review processes to assure/verify the director is performing the expected duties, tasks, and responsibilities?
4. Has the hospital assured, prior to entering into the arrangement, that there will be no duplication of services or medical staff requirements that the physician already performs or is obligated to perform without pay as a result of the arrangement?
5. Are there multiple directorships and if so, are there policies/procedures to assure that there is no duplication of actual services provided?
6. Are the terms of the directorship agreement reasonable and consistent with business practices? Factors to consider include: duration, renewal, termination, compensation review, and other relevant contractual terms.
7. Is the time spent reasonable in light of the duties to be performed?

Passing the commercial reasonableness test

Identifying and explaining the factors that promote commercial reasonableness can be a straightforward exercise. Addressing the questions raised above can help achieve that task as part of a review of many arrangements. Unfortunately, more hospitals are entering increasingly complex arrangements with physicians wherein the commercial reasonableness of particular aspects of an arrangement may not be obvious.

A classic example involves the acquisition of a medical group and direct employment of its physicians by a hospital. The individual physicians retain ownership of their medical office building for which the hospital agrees to pay them FMV lease payments. On the surface, the lease agreement appears reasonable and payment terms compliant. However, upon closer scrutiny, the medical office building contains a significant amount of vacant space for which the hospital has no current or planned use. As such, any payment by the hospital to rent the vacant space would likely fail the test of commercial reasonableness.

For the more complex arrangements, explaining commercial reasonableness will require extra analysis and documentation. The question then becomes, "Whose job is it to evaluate the arrangement—hospital management, the physicians, the attorney, or the appraiser?"

Proper documentation of commercial reasonableness is an important part of the process. Health care organizations should develop a protocol to determine the appropriate documentation policy that fits their organizational needs. As part of this process organizations should determine:

- Whether the appraiser should include a commercial reasonableness analysis for this type of arrangement.
- Whether the organization should complete the analyses in conjunction with the appraiser and counsel.
- Whether management should complete the analysis independent of the appraiser and submit to be included as an attachment to the appraiser's report; or

- Whether management should complete the analysis independent of the appraiser, and separately submit the analysis to their internal Compliance department without including it in the appraiser's report.

At present, the industry is advancing varying paths for process and documentation; however, a growing number of health attorneys are requesting outside appraisers to formally weigh in on the question and provide formal opinions.

Passing the test for commercial reasonableness is a requirement from both regulatory and practical business perspectives. Incorporating relevant analyses as part of the formation of hospital-physician relationships will improve confidence in deal-making, better explain specific arrangements, and promote compliance. ■

1. *U.S. ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, 3:05-CV-02858-MJP (D.C.S.C.); *U.S.ex rel Elin Baklid–Kunz v. Halifax Hospital Medical Center*, 6:09-CV-1002-DAB (M.D.F.L); *U.S. v. Campbell*, 2011 W.L. 43013 (D.N.J.)
2. 2011 W.L. 43013 (D.N.J.)
3. No. 04-186, 2010 U.S. LEXIS 119355 (W.D. Pa. Nov. 10, 2010)
4. 63 F.R. 1700 (1998)
5. 69 F.R. 16093 (2004)
6. Brief of Amicus Curiae American Hospital Association in Support of Defendant-Appellant, *United States Ex. Rel. Michael K. Drakeford, M.D. v. Tuomey Healthcare System, Inc.*, No. 10-1819 at 5 (4th Cir January 10, 2011)
7. Transcript of Record at 975-81 (Kathleen McNamara's expert testimony during *US ex rel. Drakeford v. Tuomey Healthcare System, Inc.*, 3:05-CV-02858-MJP (D.C.S.C.)].

OIG compliance tour yields multimedia trove of new resources

By Spencer K. Turnbull

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Being a successful compliance officer can be a challenge under the best of circumstances. And for those responsible not only for compliance, but also for an office's scheduling, billing, or management, the challenge becomes that much greater. These individuals, who must wear several different hats at smaller provider entities, are who the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) had in mind when it designed its Health Care Fraud Prevention & Enforcement Action Team (HEAT) Provider Compliance Training series (PCT), which debuted in February 2011. Although the live series has concluded, its legacy is a trove of new compliance materials designed with the busy compliance professional in mind. As stand-alone teaching aids for your staff, or as a multimedia addition to your existing training, the online resources of OIG's PCT are available to help you spread a message of compliance.

Vision of compliance outreach

OIG began planning PCT in 2010 to complement HEAT, a cabinet-level initiative launched by Attorney General Eric Holder and Secretary Kathleen Sebelius in May 2009. HEAT introduced a new effort with increased tools and resources, and a sustained focus by senior level leadership to enhance collaboration between HHS and the U.S. Department of Justice (DOJ), and build on the success of the Medicare Fraud Strike Force. But, OIG recognized that as the impressive enforcement accomplishments of the Strike Force received widespread publicity, it was also important to educate providers about the schemes uncovered by the Strike Force, and to communicate to providers who wanted to do the right thing that OIG would be engaged in helping them stay on the right side of the law.

The idea for PCT originated in the Industry Guidance Branch (IGB) of OIG's Office of Counsel. Many compliance professionals may recognize the IGB as the source of OIG's Compliance Program Guidances, Advisory Opinions, and fraud alerts. The IGB also fields public calls and letters about the Anti-kickback Statute and certain other health care fraud laws. As a result, the IGB has frequent interaction with the regulated community, and a good sense of what questions are most frequently asked by providers.

Equipped with this background, IGB attorneys set out to architect a series of compliance training programs that would provide free, high-quality compliance training for providers, compliance professionals, and attorneys in Strike Force cities and elsewhere. Their vision was to bring together representatives from agencies such as OIG, the Centers for Medicare & Medicaid Services (CMS), DOJ, and Medicaid Fraud Control Units to address local provider, legal, and compliance communities, with an emphasis on the types of high-risk fraud identified by HEAT.

Importantly, OIG intended the training sessions to reach those who often do not have the

resources to attend more expensive national conferences that are the more traditional venue for government speakers. OIG believed these smaller entities represented a missed opportunity for the government to spread its message of creating a culture of compliance and shared responsibility for program integrity. Moreover, smaller entities may be particularly susceptible to becoming unwitting partners in fraud schemes, because they lack dedicated compliance staff or a robust compliance program.

A new compliance curriculum hits the road

In order to design a comprehensive and well-rounded curriculum, IGB staff teamed with OIG colleagues, including auditors, evaluators, criminal investigators, and other attorneys. Their collaboration yielded three general themes: the fraud and abuse laws, how to avoid running afoul of those laws by having a robust compliance program, and what to do if a compliance issue arises. OIG sought to distill the broad sweep of its portfolio into a half-day program that would provide an intuitive framework for health care fraud and abuse compliance. To accompany the presentations, OIG created new educational documents to summarize key points and direct readers to the correct places to find additional resources. The resulting program included specific topics, such as navigating the government, operating an effective compliance program, an overview of CMS, and a panel discussion of health care fraud enforcement featuring federal prosecutors and federal and state criminal investigators.

The first PCT session was held in Houston in February 2011. As was the case after each session, OIG solicited feedback from the attendees to help it adjust content to improve future sessions. By the time the last in-person PCT session was held in May, OIG had refined the content of the session and created a library of educational documents for use in conjunction with the training. In all, OIG held PCT sessions in Houston, Tampa, Kansas City, Baton Rouge, Denver, and Washington DC, training a total of 737 in-person attendees. In addition, the final HEAT PCT session in Washington DC was webcast live to 2,335 participants.

Provider compliance training podcasts rolling out now

PCT continues online, offering a great training resource for all providers, compliance professionals, and their counsel. PCT training materials are now available on the Internet, together with sixteen video modules that divide the PCT webcast by subject area. These web-based training materials continue to reach the health care community with OIG's compliance message. In addition, OIG has produced eleven PCT video and audio podcasts. In contrast to the full length video modules, which cover the full, half-day PCT presentation in Washington DC, the podcasts average just four minutes in length and focus on top compliance issues. These video and audio podcasts—the first of which were posted to OIG's website in December 2011—feature OIG attorneys, along with PowerPoint® presentation slides. As standalone resources, or together with your organization's own existing compliance training, PCT gives providers numerous ways to hear directly from OIG about fraud and abuse, and compliance fundamentals. All the PCT documents, videos, and podcasts can be found at www.oig.hhs.gov/compliance/provider-compliance-training/index.asp

HCCA has stepped up our environmental responsibility by printing **Compliance Today** on recycled paper. The interior pages are now printed on paper manufactured with 100% post-consumer waste. The cover stock is made up of 10% post-consumer waste and is locally produced in Minnesota near our printing facility. In addition, the energy used to produce the paper is 100% renewable energy. This is not to mention that the ink used in our magazine is 100% soy-based water soluble ink. Certifications for the paper include The Forest Stewardship Council (FSC), Sustainable Forestry Initiative (SFI), and Green-e.org.

In Memory of

Kendra Dimond Campbell

A truly great friend, a mentor, and a research compliance industry leader

Editor's note: We have suspended the Feature Interview in this issue of **Compliance Today** *and replaced it with this memorial written by F. Lisa Murtha to honor Kendra Dimond Campbell, a true visionary who helped establish the research compliance discipline, an advocate for compliance and compliance programs, and a remarkable and genuine human being. She will be sorely missed.—Roy Snell, Chief Executive Officer, HCCA.*

I learned yesterday of the passing of my most cherished friend and colleague, Kendra Dimond Campbell. For those of you who had the privilege of knowing her, you will no doubt agree that Kendra was one of the kindest and most thoughtful people working in health care. You also know that she was one of the first attorneys who focused her practice in the areas of fraud and abuse, clinical research law, and compliance. She was a visionary—she understood (before the rest of us really did) that clinical research is one of the most fascinating areas of the law. She was a thought leader who helped create the research compliance discipline as we know it today. She will be sorely missed.

Kendra was a graduate of both Penn State University and the Dickinson School of Law (my two alma maters, by the way). She soon thereafter began her more than thirty-year legal career in Harrisburg, Pennsylvania, working with the Pennsylvania Office of Attorney General. She distinguished herself as legal counsel to Attorney General LeRoy Zimmerman, and she later transitioned to work with the prestigious law firm Duane Morris LLP. She quickly ascended to Partner and then she and her husband, Bill Campbell, moved to Washington, DC. It was there that Kendra became enthralled with the legal, regulatory, and compliance complexities associated with clinical research. She worked at NIH and focused

her attention on the areas of human research protections (working then with the Office for Protection from Research Risks). In addition to her work in human research protections, she became an expert on matters related to scientific misconduct. Moreover, she helped guide the development of many of the clinical research regulations we work with today.

Not surprisingly, many law firms sought out Kendra, and she later joined Arent Fox LLP, and later,

Epstein Becker Green LLP, where she became a "household name" in clinical research law and compliance. Kendra was a frequent presenter for organizations such as HCCA, the American Health Lawers Association (AHLA), and and the Healthcare Financial Management Association (HFMA), to name just a few.

What people loved most about Kendra's talks was that she was always genuine. There was no pretense about her, and her vast knowledge and exquisite judgment always rang through. She was the model I have tried to aspire to, as have many others in our industry. In fact, when told about her passing, Roy Snell, CEO of HCCA and SCCE, said, "I would like Kendra's family to know how much Kendra meant to our profession. She helped so many people. She spent a great deal of time teaching and guiding others through very difficult challenges they faced. She was always positive and a joy to work with. She has left an indelible mark on our profession."

Not surprisingly, Kendra was later "courted" by eminent consulting firms, including Huron Consulting Group and Daylight Forensic & Advisory. She distinguished herself yet again as a top-rated consultant. Over the last two years, Kendra wanted to get back to the "roots" of her passion, and she joined the University of Central Florida as a member of the Institutional Review Board and as the Research Compliance Officer.

I met Kendra in 1997 when we were scheduled to do a presentation together. I was a fairly green compliance officer at a large research university. We became fast friends and colleagues. I had the honor of working with Kendra on a variety of research matters over the years and she became a "big sister" and mentor to me. Much of what I have learned in this area came from her generous teachings, and I know many people who would say the same. She was the "consummate professional" and a truly classy person. I will miss Kendra's friendship for the rest of my life. She was there for me when I really needed someone I could turn to, trust, and rely on. Her guidance got me through many challenges I have faced during my career. Candidly, I do not know what I would have done without her.

Her many personal and professional accomplishments should be celebrated, and we will always remember the mark she has made on our profession, and on our lives. I hope you will join me in honoring her.

As I said, Kendra has touched our profession and our lives in so many positive ways. Her devotion to her soul mate and husband, Bill, represents the kind of marriage/relationship most people hope to have. She was also a loyal daughter, mother, sister, and grandmother. She literally beamed when she spoke of her family and I am sure they know how much she loved them. My thoughts and prayers are with them.

In Kendra's true spirit of giving, she requested that if any individuals wish to remember her, they might make a contribution to the national Alzheimer's Association (www.alz.org). Kendra's beloved father suffered from Alzheimer's until his passing, and she wanted to support efforts to eradicate this devastating disease. For those of you who want to learn more about Kendra, please view the website set up by her loving family at www.caringbridge.org/visit/kendradimondcampbell.

So, as you can see, Kendra was truly a remarkable person, and I feel so privileged to have known her. Her many personal and professional accomplishments should be celebrated, and we will always remember the mark she has made on our profession, and on our lives. I hope you will join me in honoring her. ■

External risk assessment tool for inpatient rehabilitation facilities

By Bill Moran and Catie Heindel, JD

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In its Compliance Program Guidance for Hospitals,[1] the Department of Health and Human Services, Office of Inspector General (OIG) asks the question, "Has the Hospital developed a risk assessment tool, which is re-evaluated on a regular basis, to assess and identify weaknesses and risks in operations?" As each type of health care organization has its own unique risks, risk assessment tools may vary in content and design. However, depending on the type of care provided by your organization, there are certain risks that are always present and must be addressed. This is definitely the case when examining risks for Inpatient Rehabilitation Facilities (IRFs). This article will outline one method for developing a risk assessment tool for IRFs.

Importance of IRF risk assessment

Prior to undertaking the job of developing an IRF risk assessment tool, organizations should briefly remind themselves of the importance of such a task. To begin, facilities always want to ensure that they are providing the best possible care to their patients, in accordance with professional and governmental standards. Second, since health care organizations operate in a finite budgetary environment, it is vital to mitigate those risks that are most damaging to the finances and reputation of the institution, and are most probable to be found by external enforcement agents. Finally, because no organization has the resources or ability to audit every risk it has, it is important to thoughtfully choose among risk options and be judicious with any expenditures not directly related to patient care.

Elements of IRF risk assessment

Every risk assessment should focus on both internal and external risks. Internal risks are those that exist within the organization due to weaknesses in policies, procedures, systems, and personnel. Organizations learn about internal risk through audits, work groups, and observing daily interaction with policies and procedures. Because internal risks are unique to every organization, suffice it to say that these risks need to be identified and recounted when prioritizing and considering overall risk to the organization.

External risks are those that exist outside the organization and can be separated into two categories: regulatory risk and environmental risk. Regulatory risk areas can be identified by reviewing the laws, regulations, policies, and guidance promulgated by governmental entities for IRFs. Once these areas of regulatory risk are identified, organizations should examine and observe how these rules are enforced by the government and those acting on behalf of the government. The risk assessment tool proposed in this article will focus primarily on the different external risks for IRFs.

External regulatory risk areas

As mentioned earlier, to conduct a robust external IRF risk assessment, it is important to identify and record the universe of IRF regulatory risk areas, noting the written reference and a brief description for each risk area. Because there are number of regulatory risk areas, it may be easier

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to divide the risk areas into major categories, which might include:

- Conditions for Coverage/ Conditions of Participation (e.g., Medicare Hospital Provider Agreement; Discharge Disposition notice)
- Medical necessity (e.g., the three-hour rule; Medicare admission criteria)
- Billing integrity (e.g., case-level payment adjustments—early transfers; clinical research billing)
- Records management (e.g., clinical record entries; hospital admission and discharge records)

Multiple risks exist within each of these categories, and there should be a brief, one or two sentence description of each risk identified.

In addition to noting the risk category, risk area, citation or reference, and brief description of the risk, organizations may want to add other indicators to its tool, such as linkage to internal risk areas, risk in previous years, special mitigation efforts in process, and rank (e.g., high, medium, low or 1-5). Each of these indicators can be placed on a spreadsheet for easy viewing (See table 1 on page 19). Please note that this is only a sample list of a few regulatory risks, and there are many more to be considered.

External environmental risk areas

It is also important for organizations to consider the risks presented by the various government enforcement entities and those acting on their behalf. Risks associated with enforcement activities may be displayed in categories that might include the most recent OIG Work Plan, reports from the OIG Office of Audit, OIG Office of Evaluations and Inspections, OIG announced investigations, Centers for Medicare & Medicaid Services (CMS) major program updates, health care reform legislation, recent Congressional testimony, and recent government and industry conferences. Again, under each of these would be an identified risk area, citation or reference, and brief description. You may also want to prioritize the risk for each risk area (See table 2). Again, please note that this is only a sample list of a few environmental risks, and there are many more to be considered.

The use of a strong risk assessment tool is essential for prioritizing an organization's risks, which in turn, helps to design a plan to mitigate the most important risks through revised policies and procedures, education for staff, and then monitoring and auditing those risk areas. Once performed, the risk assessment is a valuable tool for informing the executives in the organization and the board of directors about where the most vulnerable parts of its operation reside. This type of information is essential for executive and board members to understand in order for them to perform their oversight and accountability duties. A robust risk assessment is an invaluable tool for governance. It makes sense to do it right.

1. Fed Reg vol 63, no 35, February 1998. Available at http://oig.hhs.gov/authorities/docs/cpghosp.pdf

Table 1: IRF External Regulatory Risk Identification Tool

EXTERNAL REGULATORY RISKS			
Risk Area	**Citation/Reference**	**Description of Risk**	**Ranking**
Conditions for Coverage/Conditions of Participation			
Classification of IRFs - 60% Rule (changed in 2010 Rule, from 75%)	42 CFR §412.29(b)(1)-(2); Medicare Benefit Policy Manual (100-02), Chapter 1, Section 140.1.1.	IRF does not meet required threshold for CMS-13 qualifying discharges as a percentage of all discharges	3
		Inaccurate assignment of impairment or qualifying diagnosis code	1
Medical Necessity			
3-hour rule (therapy services)	42 CFR § 412.622(a)(3)(ii)	Failure to furnish intensive therapy services 3 hours a day, at least 5 days a week, during patient's IRF stay	2
Billing Integrity			
Billing for non-employed providers	42 CFR § 412.604(e)	Inappropriately billing for inpatient services performed by non-employed providers (e.g., nurse practitioners, radiologists, etc.)	1
Incorrect discharge status code	42 CFR §412.624(f); Claims Processing Manual (100-4), Chapter 3, Section 140.2.3; CMS MLN. "Medicare Quarterly Provider Compliance Newsletter Guidance to Address Billing Errors." Apr. 2011.	Failure to use proper status code for patients transferred from an IRF to another rehabilitation facility, a long-term care hospital, an inpatient hospital or a nursing home.	2
Records Management			
Clinical record entries	42 CFR §412.23(b); 42 CFR §412.29(i).	Failure to have periodic clinical entries in the patient's medical record that indicate the use of a coordinated interdisciplinary team approach in the rehabilitation of each inpatient.	3

Table 2: IRF External Environmental Risk Identification Tool

Table 2: External Environment Risk Areas			
Risk Area	**Citation or Reference**	**Brief Description**	**Rank**
HHS OIG Work Plan			
IRF admissions	HHS OIG Work Plan 2012. "In-Patient Rehabilitation Facilities."	Failure to ensure appropriateness of admissions to inpatient rehabilitation facilities (IRFs).	1
Level of therapy provided	HHS OIG Work Plan 2012. "In-Patient Rehabilitation Facilities."	Failure to monitor the level of therapy provided for beneficiaries in IRFs, specifically focusing on how much concurrent and group therapy is being provided.	2
OIG Audit and Evaluation Reports			
IRF claims with transfer code 05.	HHS OIG. "Review of Jurisdiction 5 Payments for IRF Claims Billed with Patient Status Code 05 for Calendar Year 2007." (A-01-10-00518). Feb. 2011.	IRFs incorrectly coded 24 of the 53 claims that we reviewed with patient status code 05. These beneficiaries were actually transferred to facilities that were subject to the Medicare transfer regulations, e.g., inpatient hospitals, skilled nursing facilities, and Medicaid-only nursing homes.	3
Recent Congressional Testimony			
Medical necessity/ Appropriateness of service site for post-acute care	MedPAC's Annual March Report to the Congress on Medicare Payment Policy. Committee on Way and Means. Subcommittee on Health. United States House of Representatives. 17 March 2009.	This report discusses ways to lower the costs of post-acute care. The testimony of Glenn Hackbarth, the Chairman of MedPAC, focuses on medical necessity/appropriateness of care setting for the provision of post-acute care, asserting that the level of care provided in inpatient rehabilitation hospitals and long-term care hospitals are not medically necessary after a hospital admission.	2

Letter from the CEO

For the sake of completeness, innocent people can be hurt

When accusations are made, there are two ways to mess it up: to not react or to overreact. For the sake of completeness, some people create unwarranted stress. Society's reaction to the regulatory compliance and ethics problems in business is appropriate. The pendulum is swinging from loose controls and limited oversight to tighter controls and stronger oversight. A risk we face, however, is letting the pendulum swing too far the other way.

There are cries to report any problem that anyone thinks they see. This is a good thing. However, the cries for immediate and crushing investigations of every allegation brought forward may on occasion be unwarranted. Good people can be hurt when the allegations are found to be wrong only after an overreaching investigation. I understand there is a fine line between doing too much and doing too little. On occasion, not enough is done to substantiate allegations early on. A question should be asked every day: "Can we draw our conclusion today?" Instead, some people say, "For the sake of completeness, we have to beat this to death."

Some people intentionally make false allegations. There are people who, for whatever reason, just like to lob hand grenades into a room and run away. There are people who feel they have been wronged and use the compliance program to inflict their pain on others. There are also well-intentioned people who make accusations and are simply mistaken. This can become a problem if you combine it with people who play the "completeness card" to the hilt.

We need to use common sense and strength to take a more measured approach. Whenever possible, we need to give people a chance to defend themselves before they are put through the wringer. We need to take into consideration the track record of the accused. Society seems to think that all accusers are victims. Society needs to realize that some of the accused are victims too. Compliance professionals hold in our hands the ability to protect the falsely accused as well as find and fix problems. We must remember we are neither a prosecutor nor a defender. We don't ignore or leave out facts that point to innocence. We don't ignore or leave out facts that point to guilt. We simply prevent, find, and fix problems by gathering facts and assuring that action is taken when necessary. ■

We simply prevent, find, and fix problems by gathering facts and assuring that action is taken when necessary.

If you have any questions that you would like Roy to answer in future columns, please e-mail them to: roy.snell@hcca-info.org.

Social Networking

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HCCAnet® functions like any other online community that shares common interests. The site has multiple communities that members can access, such as Auditing and Monitoring, Chief Compliance/Ethics Officers, Long-term Care, Hospital, Research Compliance, and other networks and forums. The social networking site is a great way to make friends, talk with peers, and focus on a specific compliance topic. Here are some recent topics from discussion groups:

1. Auditing and Monitoring Compliance
2. Chief Compliance Ethics Officer
3. Competition Law and Antitrust
4. Compliance Book Club
5. Compliance Diversity Forum
6. Compliance Risk Management
7. Educators Forum: Teaching Compliance
8. Ethics Forum
9. European Compliance and Ethics
10. FCPA: Foreign Corrupt Practices Act
11. Global Compliance and Ethics
12. Higher Education Forum
13. Insurance Network
14. Investment Management Forum
15. Legal Holds and Record Management
16. Nonprofit Network
17. Privacy Officer's Roundtable
18. Privately held Corporations
19. Product Review Forum
20. Quantitative Compliance

To participate in the discussion, review the comments, or just talk with your peers, you can access the HCCAnet® by going to the following link: http://www.hcca-info.org/hccanet ■

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Exhale

By Shawn DeGroot

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The stress of information

Recently, a clip of a two-year old was on the television, revealing how technology has impacted life at a very early age. The child was holding a book and attempting to shrink the pictures on the cover and flip the page by sliding her fingers. After several attempts, the child appeared to be puzzled and somewhat frustrated. She set the book aside, never opening the paper pages.

To me, there is something precious about a paper or hardcover book that I can hold, tab the pages, or underline sections. I recently challenged myself to try reading a book on an iPad2. I downloaded a biography of Steve Jobs[1] and *The Innovator's Prescription: A Disruptive Solution to Healthcare*[2] and discovered the attraction of e-books. Fundamentally, the fact that the pages are lighted allows me to read longer and the lighting is a definite benefit when on an airplane. I am not sure there is anything seductive about reading regulations on an e-book; however, I will probably join the ranks of those who do!

Next, let's think about the speed at which technology and social media disseminates information and real time events. The amount of information we absorb on a daily basis is daunting. LinkedIn, Facebook, Twitter, professional email, and personal email are quickly replacing face-to-face meetings. While scheduling is easier or the cost of travel may be reduced, there is still great value in human interaction. Landline telephones are being replaced with cell phones, all making society very mobile and connected.

Furthermore, it wasn't too many years ago that we all relied on the local newspaper to remain abreast of issues, breaking news on legal issues, and world events. We are now hardwired into receiving video within seconds of an event from anywhere in the world and reading multi-city newspapers online. One essentially could read new information on a computer 24/7 and never read it all.

Another fascinating change is the DVR technology that allows skipping through commercials (excluding the Super Bowl commercials, of course) and rewinding specific plays of a football game. Rewinding plays and interviews creates more factual circumstances on which to base findings and conclusions. Wouldn't it be nice to rewind and play back points of determination on compliance issues? The length of time needed to investigate an issue would be dramatically reduced.

As a society, we have transformed from paper notices to electronic communication in a very short order. When compliance professionals were asked "What is the greatest cause of stress?" in the HCCA/SCCE stress survey, 24% responded it is keeping up with new laws and regulations, preventing compliance and ethics violations, and remediating compliance and ethics violations. While there are true benefits to accessing information electronically, the abundance and speed of receiving that information could be overwhelming, if we don't face the fact that we will never know it all or be aware of every piece of information we should have or could have read. Rather than feel overwhelmed—inducing yet one more level of stress with high expectations of reading it all—register one thought in your subconscious to rewind and replay: "*We are in the Compliance field for the right reason and with good intent.*" ■

1. Walter Isaacson: *Steven Jobs*. Simon and Schuster, 2011
2. Jerome H. Grossman, MD and Jason Hwang, MD: *The Innovator's Prescription: A Disruptive Solution for Health Care*. McGraw-Hill, 2008

Developments in telehealth: A brave new compliance world

By Rene Quashie, Esq. and Amy Lerman, Esq.

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Telehealth continues to be a fast growing practice in the health care industry, with increasing numbers of health care providers relying on telehealth services and technologies to provide quality patient care efficiently and cost-effectively. Telehealth has progressed from complex technological systems to a systematic integration of health care services delivered through commercial off-the-shelf components. No longer a practice modality largely rejected by clinicians, telehealth services are utilized more than ever before. Through the use of telehealth, patients in rural and remote communities who regularly encounter geographic and/or economic obstacles to obtaining quality health care can access a more robust spectrum of health care services and providers.

Unfortunately, telehealth has advanced faster than the law. As technology generally has developed, health care providers increasingly have identified opportunities to engage with patients via less traditional methods. However, little guidance exists to prepare and guide health care providers through the various legal, regulatory, and reimbursement issues that often arise when providing telehealth services.

Credentialing, privileging, and licensure challenges

Historically, two of the most significant barriers to the practice of telehealth have been the credentialing and privileging of telehealth providers and cross-state licensure issues. Licensure continues to be a significant compliance hurdle for many telehealth providers as they are forced to navigate the different licensure requirements of multiple states in order to provide telehealth services. However, a recent final rule issued by the Centers for Medicare & Medicaid Services (CMS) takes an important step toward streamlining the credentialing and privileging processes for providers of telehealth services. Despite progress in the area of credentialing and privileging, however, licensure hurdles remain.

The final rule issued by CMS, effective July 5, 2011, allows hospitals and critical access hospitals (the "patient site") to rely on the credentialing and privileging of a "distant site" provider for practitioners providing telemedicine services.[1] CMS has stated that a distant site may include both Medicare-participating hospitals and telemedicine entities (i.e., tele-radiology providers and physician practices). Compliance with this provision requires a detailed written agreement between the patient site and the distant site that is subject to disclosure by CMS. The agreement must include specific elements and evidence of the telemedicine provider's privileges and must be provided by the distant site to the patient site.

Additionally, under the final rule, the definition of "telemedicine" has changed, and now is the "provision of clinical services to patients by practitioners from a distance via electronic communications." Under this definition, telemedicine services need not necessarily be provided in real time and, instead, can be performed either simultaneously (e.g., tele-ICU) or non-simultaneously (e.g., tele-radiology).

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Practically speaking, the CMS final rule imposes several compliance considerations on health care providers who choose to adopt and incorporate telehealth. First, patient site providers should consider amending their medical staff bylaws to reflect the notion that the patient site may rely on the credentialing and privileging of providers as verified by the distant site provider. Second, distant site providers or entities offering telehealth services should review and update, or establish for the first time, policies and procedures related to credentialing and privileging of telehealth providers. Third, both patient site and distant site providers should consider the privacy implications of sharing information, not only regarding credentialing and privileging of telehealth providers, but also any information shared as a result of providing telehealth services. Finally, both patient site and distant site providers should evaluate mechanisms for sharing potential risk and diligence controls.

Telehealth coverage and reimbursement challenges

Generally speaking, payers have not embraced telehealth services in a meaningful way, resulting in poor or, in some cases, a complete lack of coverage for such services. Limitations on reimbursement for telehealth services have made many providers unwilling to offer telehealth services.

Historically, Medicare's coverage of telehealth services has been restrictive and specific. The Balanced Budget Act of 1997 authorized very limited coverage and reimbursement for telehealth services and prompted efforts towards expansion and revision of Medicare's reimbursement policies. The Benefits Improvement and Protection Act of 2000 included amendments to the Social Security Act and removed some of the prior constraints, yet maintained substantial limitations concerning geographic location, originating sites, and telehealth services eligible for Medicare coverage. Under Medicare, reimbursement for telehealth services is generally on par with reimbursement for the same services when provided face-to-face, but a number of limitations apply, including:

- a limitation on reimbursement to real-time interactive audio-video telecommunications (not "store-and-forward" technologies);
- a limitation on reimbursement to services provided to a Medicare beneficiary located at an eligible site in specified geographic areas;
- a limitation regarding the sites where a Medicare beneficiary may be located when receiving telehealth services; and
- a requirement that claims submitted for telehealth reimbursement use the GT or GQ modifier along with the appropriate billing code.

More generously, a number of states provide some form of Medicaid reimbursement for telehealth services. According to the Center for Telehealth & e-Health Law, 39 state Medicaid programs currently provide at least some reimbursement for telehealth services. Other state Medicaid agencies are amenable to establishing or enhancing telehealth reimbursement policies but face serious budget constraints that require the addition of any new coverage or services be based on cost and benefit data.[2] Because the federal government does not mandate reimbursement for telehealth services under Medicaid, states have the flexibility to reimburse for Medicaid services furnished through telehealth. Each state has separately determined what telehealth services, if any, are eligible for Medicaid reimbursement. For those states that do offer telehealth reimbursement, relevant issues affecting telehealth coverage and reimbursement include whether the service qualifies as one of the state's Medicaid covered services (or whether it would be considered an optional service), and whether there are specific requirements that providers must follow when submitting claims for services furnished using telehealth.

In addition to Medicaid coverage, some states have enacted legislation requiring private sector insurance companies to pay for

telehealth services. However, while the coverage requirement is mandatory in these states, not all require reimbursement rates on par with rates for equivalent face-to-face services. Among the various private payers providing coverage for telehealth services, Blue Cross Blue Shield has been long been a leading insurer in covering and paying for the use of telehealth services.

Providers of telehealth services should also take notice of legislation passed recently in California, as it may provide a potential model for other states to expand payer coverage for telehealth services. California's Telehealth Advancement Act (TAA), was signed into law in October 2011 and became effective on January 1, 2012.[3] Among other things, the TAA replaces the outdated terminology of "telemedicine" with the term "telehealth" and updates the definition of telehealth to broadly reflect the technology-enabled delivery of services, rather than specific types of medical practice. Additionally, the TAA applies the updated definition of telehealth to all licensed health professionals and further expands the definition of "health care practitioner" to include all medical professionals licensed by the state of California. The TAA removes limits on the physical locations where telehealth services may be provided to allow for any type of telehealth service to be covered—regardless of where it takes place. The TAA will permit all types of store and forward services, patient care management programs, caregiver support programs, provider service delivery programs and patient education programs. The TAA also modifies the existing requirement for an additional written patient consent specific to provision of telehealth services and permits verbal patient consent. Additionally, the TAA eliminates restrictions on reimbursement of services provided via email or telephone.

Finally, the TAA modifies some existing regulations that affect provision of telehealth services under the Medi-Cal program. The TAA:

- eliminates an existing Medi-Cal requirement for documentation of a barrier to an in-person visit before a beneficiary can receive telehealth services; and
- removes a twice-extended sunset date in Medi-Cal that would have eliminated Medi-Cal coverage of store-and-forward services for tele-dermatology, tele-ophthalmology and tele-optometry.

The intended consequence of the TAA is to allow coverage of, and reimbursement for, a broader range of telehealth services than was previously allowed. Notably, the broad parameters of the TAA will not limit the addition of future telehealth technologies and services as they are developed. Most importantly, the TAA takes important steps toward establishing parity between health care services provided in-person and those provided via telehealth. Payers that provide coverage in California will need to adjust current coverage and reimbursement policies for telehealth services to reflect the changes required by the TAA.

An expansion of coverage for telehealth services may create compliance considerations for health care providers who offer such services. Payers use a variety of factors to determine the scope of coverage for telehealth applications and services, such as the quality of the equipment, the type of services to be provided, and the location of the providers. Should states other than California begin to adopt telehealth policies and regulations similar to those in California, coverage and reimbursement parameters will continue to evolve. At a minimum, providers should presently consider conducting a regulatory analysis of the relevant states' requirements for provision of telehealth services to ensure that the operational and technological elements of providing such services meet the current requirements imposed by the various payers that provide coverage and reimbursement for the services. Providers should also examine their current payer

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contracts to understand the coverage limitations for telehealth and, if necessary, push for broader coverage policies as these contracts come up for renewal.

Technical challenges for telehealth providers

Health care organization executives, while enthusiastic about the benefits of telehealth technologies, have competing concerns about issues such as data security and the need for uniform control measures across various types of technology. One of the biggest concerns commonly voiced by health care executives regarding telehealth involves how best to keep patient information confidential, and just as significantly, their respective organizations in compliance with all the federal and state privacy and security statutes and regulations.

Beyond the overarching data privacy and security considerations for providers to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), certain other compliance considerations are unique to telehealth providers. One such challenge is determining the level of security built into the various telehealth technologies (such as Skype and similar web and videoconferencing technologies). Also, providing telehealth services may require the participation of non-clinical personnel, such as technicians and camera operators, who are not traditionally part of patients' health care encounters. Health care organizations must develop and implement telehealth-specific protocols, not only to ensure that patients are informed about all potential participants in telehealth encounters, but also to ensure that the privacy and security of patient data is maintained.

Health care organizations must evaluate whether business associate agreements with these non-clinical providers (non-covered entities) are needed. Finally, health care organizations must contemplate whether providers of telehealth services require HIPAA privacy training and education (if the provider is a member of the patient site workforce), as well as whether to distribute its Notice of Privacy Practices to patients receiving services at the distant site.

Overall, health care organizations that anticipate using telehealth to provide health care services will need to seriously consider implementing the compliance measures discussed above. Organizations may need to consider to what extent relevant policies and practices already exist, and whether it would be worthwhile to manage and enforce such policies and practices separately from comparable policies and practices applicable for face-to-face services. All in all, it is apparent that utilization of telehealth services will only increase, thus requiring that health care organizations adjust their compliance approach accordingly. ■

1. 76 Fed. Reg. 25550 (May 5, 2011).
2. See http://www.ctel.org/expertise/reimbursement/medicaid-reimbursement/
3. A.B. 415, 2010-2011 Leg. (Cal. 2011).

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Articles related to the quiz in this issue of **Compliance Today**:

- **Promoting commercial reasonableness in hospital-physician relationships**—By Christopher G. Fete, Drew Hoffman, and Daniel P. Stech, page 6
- **The role of compliance in the quest to improve patient experience**—By Lisa Venn, page 28
- **On mentoring**—By John E. Steiner and Alan Peterson, page 51

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The role of compliance in the quest to improve patient experience

By Lisa Venn, JD, MA, CHC

Editor's note: Lisa Venn is the owner of Advocate Alliance in Cleveland, Ohio. She may be contacted by e-mail at Lisa@advocatealliance.net.

The race is on. Effective fiscal year 2013, the Centers for Medicare & Medicaid Services (CMS) will factor in patient experience survey results when determining payment for Medicare hospital discharges occurring on or after October 1, 2012.[1] Under this Hospital Value-Based Purchasing program, payments to high performing hospitals will be larger than those to lower performing hospitals.

In the quest to improve patient experience scores, thus increasing Medicare reimbursement, some health care providers are seeking guidance from customer service giants like Disney and Ritz-Carlton. Although we have much to learn from these business icons, blind adherence to their practices is legally risky.

Compliance officers must communicate an important message: In the quest to improve patient experience, we must adhere to laws that dictate how we market, survey, pursue service recovery, and respond to patient complaints.

Imitation-worthy practices

Health care providers can confidently follow the practices of customer service experts who recognize and act upon the value of every customer, viewing each interaction as an opportunity to create customer loyalty. Their leaders invest considerable time and money to hire, train, coach, and reward employees for excellent customer service. They also recognize that engaged and valued employees provide great service. Because employees are valued, they are proud of and loyal to their organizations. The resulting low employee turnover enables service consistency and development of long-standing relationships between employees and repeat customers.

Marketing limits

Marketing to future needs is a key component of customer satisfaction in the non-health care arena. Some customer service experts stress the importance of sending a thank you card, including a gift of some sort as an incentive to do business again. In the health care arena, however, the federal government considers some complementary extras "kickbacks."

The Anti-kickback Statute (AKS)[2] prohibits the knowing and willful offer, solicitation, payment, or receipt of anything of value that is intended to induce (1) the referral of an individual for which a service may be made by Medicare and Medicaid or certain other federal or state health care programs; or (2) the ordering, purchasing, leasing or arranging for, or recommending the purchase, lease, or order of, any service or item for which payment may be made by such federal or state health care programs. An individual who violates the AKS may be subject to criminal prosecution and administrative penalties under the Civil Monetary Penalty (CMP) Statute.[3] Most states have anti-kickback statutes, which often apply to items or services provided by other payers.

Marketing by or for health care providers is subject to intense scrutiny by the Department of Health and Human Services (DHHS) Office of Inspector General (OIG). OIG views marketing as inherently suspect, because its purpose is to recommend

products, services, and/or providers. The AKS contains a number of exceptions called safe harbors,[4] but there is no such protection for marketing.

OIG has interpreted the prohibition to permit Medicare or Medicaid providers to offer beneficiaries inexpensive gifts (other than cash or cash equivalents) or services without violating the statute. For enforcement purposes, inexpensive gifts or services are those that have a retail value of no more than $10 individually, and no more than $50 in the aggregate annually per patient.[5]

Patient survey limits

To improve, retain, and develop business, customer service experts recommend obtaining customer feedback through online, in person, or traditional mail surveys.

Before adopting this no-holds-barred survey approach, health care providers take heed: CMS, which implemented the Hospital Consumer Assessment of Health care Providers and Systems (HCAHPS) survey, limits the use of other surveys by hospitals. To ensure that the HCAHPS process is untainted, CMS prohibits hospitals from giving inpatients any survey during their hospital stay or at the time of discharge.[6] CMS permits hospitals to ask patients about their hospital experience during their hospital stay or during discharge calls, as long as doing so is a normal part of clinical rounds, leadership rounds, or patient treatment/care activities. CMS cautions providers against asking questions that resemble HCAHPS items or their response categories.

Service recovery limits

When things go wrong, customer service leaders empower employees at every level to make it right, whatever it takes. Their employees send gift baskets or write off tabs to keep customers coming back. In health care, giving gifts or writing off copayments and/or deductibles may violate state and federal anti-kickback laws.

There are legal limits to the value of service recovery items health care providers may give patients. In its July 2008 Advisory Opinion, OIG addressed a provider's proposal to give $10 gift cards to patients whose service expectations were not being met.[7] An OIG Advisory Opinion, which is only binding on the provider asking the question, offers valuable guidance to others considering a similar arrangement. OIG reasoned that this service recovery effort was permissible because:

- the value of the cards did not exceed $10;
- the cards were only redeemable at specific vendors that do not sell items or services paid for by federal health care programs; and
- they were not redeemable for cash or for items or services provided by the one giving the cards.

OIG noted that the provider planned to implement a system for tracking the issuance of the cards to ensure a beneficiary does not receive multiple cards having an aggregate value in excess of $50 per year.

Copayment/Deductible write-off restrictions

Dissatisfied patients may demand that the provider write off the copayment or deductible owed under the patient's insurance coverage. The Medicare "deductible" is the amount that must be paid by a Medicare beneficiary before Medicare will pay for any items or services for that individual. "Copayment" or "coinsurance" is the portion of the cost of an item or service which the Medicare beneficiary must pay.

Providers that routinely waive the copayments and/or deductibles of unhappy patients may risk violating the AKS and be liable for civil monetary penalties. The AKS allows for non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts.[8] An OIG Special Fraud Alert

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(December 19, 1994) states "When providers, practitioners or suppliers forgive financial obligations for reasons other than genuine financial hardship of the particular patient, they may be unlawfully inducing that patient to purchase items or services from them."[9]

OIG explains that routine waivers of deductibles and copayments are unlawful because they result in (1) false claims; (2) violations of the Anti-kickback Statute; and (3) excessive utilization of items and services paid for by Medicare.

Patient grievance requirements
When addressing patient concerns, employees at every level must understand the hospital's patient grievance process. CMS mandates that all hospitals have policies and procedures to ensure timely investigation, response and follow up on all patient grievances.[10] CMS's definition of "grievance" is so broad that it includes the majority of patient concerns. The Interpretive Guidelines define grievance as any concern:

- about patient care that cannot be resolved at the time of the concern by staff present, is postponed for later resolution, is referred to other staff for later resolution, requires investigation, and/or requires further action for resolution;
- alleging abuse or neglect;
- pertaining to the hospital's compliance with CMS's Conditions of Participation;
- pertaining to a Medicare beneficiary discharge dispute;
- that a patient requests to be handled as a formal complaint or grievance;
- regarding Medicare billing/coverage issues; and/or
- involving patient care.

Other grievances include a patient survey response with an attached concern and request for resolution, as well as a patient survey response with an attached concern which would normally be considered a grievance, regardless of whether the patient requests resolution.

Hospitals must follow up in writing on all patient grievances. The follow-up letter must include the:

- name of the hospital contact person,
- steps taken on behalf of the patient to investigate the grievance,
- results of the grievance process, and
- date of completion.

Hospitals must collect, analyze, and incorporate grievance and non-grievance information into the hospital's Quality Assessment and Performance Improvement Program.

Finally, hospitals must maintain documentation of its efforts to demonstrate compliance with CMS's patient grievance requirements.

Conclusion

While striving to improve patient experience, we must recognize that legal limitations on marketing, survey, service recovery, and patient complaint resolution efforts separate us from non-health care customer service giants. Compliance officers play a critical role ensuring health care providers stay in the right lane of the customer service track. ■

1. Hospital Inpatient Value-Based Purchasing Program, 76 Fed. Reg. 26490 (May 6,2011) (to be codified at 42 C.F.R. Parts 422 and 480)
2. 42 U.S.C. §1320a-7b(b)
3. 42 U.S.C. §1320a-7a(a)
4. AKS Safe Harbors are found at 42 C.F.R. §1001.952
5. OIG Special Advisory Bulletin "Offering Gifts and Other Inducements to Beneficiaries," August 2002
6. CMS CAHPS Hospital Survey Quality Assurance Guidelines, March 2011
7. OIG Advisory Opinion No. 08-07
8. This exception can be found at 42 CFR §1001.952(k)
9. OIG Special Fraud Alert (December 19, 1994)
10. 42 CFR §482.13(a)(2)

feature focus

Overview of health care fraud laws

By Richard E. Moses, DO, JD; Michelle Moses Chaitt, Esq; and D. Scott Jones, CHC

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The largest single purchaser of health care in the world, the Medicare and Medicaid programs provide a lucrative field for illicit profit through health care fraud. The National Health Care Anti-Fraud Association estimates conservatively that fraud involving these programs accounts for at least $60 billion per year.[1] Compliance in the health care area has become more important in recent years, as the federal government has ramped up its efforts to combat the violations rampant in these programs. Governmental agencies have become very creative in applying and developing legal theories and laws to combat health care fraud and abuse. Prevention of health care fraud is key to any health care organization, because the fines for violations have the potential to be millions of dollars.

The role of the compliance officer has become essential to health care organizations to prevent potential violations of the ever increasingly complex rules and laws relating to the delivery of health care. As such, the ranks of compliance officers have seen growth at a rapid pace.

The new compliance officer is immediately exposed to numerous laws that address health care fraud involving the Medicare and Medicaid programs. The basic laws and legal theories pertaining to health care fraud are readily referred to by employers, attorneys, physicians, and other health care providers in articles published in **Compliance Today** and other journals, during committee meetings, at national conferences, and in many other related venues. In addition, the Patient Protection and Affordable Care Act of 2010 (PPACA) and the Health Care and Education Reconciliation Act (collectively known as the Health Care Reform Act) significantly expanded government efforts to prevent and/or prosecute health care fraud, waste, and abuse through several key provisions that impact federal fraud and abuse provisions.[2]

This article provides a brief and general overview of the three major statutes specifically enacted and/or utilized by the government to pursue actions against entities to address Medicare and Medicaid fraud. These include the Federal False Claims Act,[3]

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the Physician Self-Referral Laws (aka the Stark Laws),[4] and federal Anti-kickback Statute,[5] and pertain to entities participating in the Medicare and Medicaid programs that provide care and services to this population of patients. The compliance officer should be aware that there are other federal laws that may also be applied to health care fraud prosecution, either alone or in combination with the three laws discussed in this article.

Federal False Claims Act

The federal False Claims Act (FCA, also known as the Lincoln Law) is a civil penalty statute. Like its companion criminal law provision (18 U.S.C. § 287), it was enacted in 1863 during the Civil War to address the problem of rampant war contractor fraud in supplying goods to the Union Army. The original FCA contained civil and criminal penalties; however, amendments in 1872 separated these provisions. The FCA remained dormant after the Civil War until amendments in 1986 reformed the Act, expanding it to include Medicare and Medicaid programs, thereby making it a formidable weapon to combat fraud on the government.[6]

The FCA covers any federally funded program or contract. It establishes liability for any person or entity that knowingly presents or causes to be presented a false or fraudulent claim for payment to the United States government, or should have known that the claim was false or fraudulent. Under the civil FCA, no specific intent to defraud is necessary. The terms "knowing" and "knowingly" mean a person has actual knowledge that the information being submitted is false, is acting in deliberate ignorance of the truth or falsity of the information, or is acting in reckless disregard of the truth or falsity of the information.

The FCA attaches a civil liability to any person or entity who knowingly files a false or fraudulent claim for payment to any federally funded program (including Medicare and Medicaid), knowingly makes or uses a false record or statement material to a false or fraudulent claim to obtain payment, and/or conspires to commit a violation that defrauds Medicare or Medicaid by attempting to have a false or fraudulent claim paid. Some general examples of false or fraudulent claims include charging for a service not provided, overcharging for a service or product provided, delivering less than the service or product promised, charging for a product or service and then providing an item that is worth a lesser amount, or underpaying or not paying money owed to the government.

The civil FCA contains a whistleblower, or *qui tam*, provision that allows a private party/citizen to file a lawsuit on behalf of the United States, and entitles that whistleblower to a percentage of any recovery (ranging from 15% to 30%) plus expenses and attorneys' fees, depending on the circumstances. The whistleblower provision is meant to encourage a person with knowledge of fraud to expose it. Whistleblowers have become important to the government in health care fraud litigation over the past few years.[7] These individuals may include employees, former employees, business associates, and present/former competitors.

Filing a false claim may result in fines from $5,500 to $11,000 per claim filed plus three times the amount of damages that the government sustained during the illegal act. Under the civil FCA, each service or item billed to Medicare of Medicaid counts as a single claim. Ostensibly, case settlements and verdicts total in the millions of dollars. In addition to the civil federal FCA, there is also a criminal federal FCA[8] that imposes criminal penalties including fines and imprisonment. Also, many states have enacted statutes mirroring the federal FCA. These provide a civil remedy for the submission of false and fraudulent claims to state health programs, including Medicaid.

Anti-kickback Statute

Although the majority of health care fraud and abuse enforcement has centered around false claims, the bribes and kickbacks provision of the fraud and abuse statute has become more important and powerful over the past 30 years. The Anti-kickback Statute (AKS) has been in force since 1972. However, it was not until the 1985 landmark case of *United States v. Greber* that the Third Circuit Court of Appeals held that physicians who had referred patients for 24-hour cardiac holter monitor services and were paid "interpretation fees" or "consultative fees" had violated the statute, because one apparent purpose of the fee payment was to induce referrals, "even if payments were also intended to compensate for professional services."[9] OIG and circuit courts readily adopted this interpretation of the statute.

Although criticized by some attorneys and legal scholars, OIG has justified the AKS in health care to the point that it is also illegal to provide kickbacks to patients.[10] The government has mandated that decisions by a health care provider involving patient care and subsequent referrals are to be based on independent judgment, based solely on the best interests of the patient, such that the second provider is the most appropriate source of services or items needed by the patient. OIG believes that kickbacks in health care lead to corruption of medical decision-making, overutilization of services, patient steering, increased costs to programs, and unfair competition. The government sees the taking of money or gifts from a referral source as simply illegal, even if the medication, service, or item of durable medical equipment would have been ordered or prescribed otherwise.

The AKS provides criminal penalties for certain acts involving Medicare and Medicaid reimbursable services, making it a felony for a person to knowingly and willfully solicit or receive, or to offer or pay, any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referral of a patient or for purchasing, leasing, ordering, arranging for, or recommending items or services paid for in whole or in part under a federally funded or state health care program. Administrative sanctions and criminal penalties for violating the AKS include fines, imprisonment, and exclusion from the federal health care programs.

In addition, OIG may seek a penalty of up to $50,000 for each improper act plus three times the total amount of remuneration involved against an individual or entity that engages in a prohibited remuneration scheme, and/or imprisonment of not more than five years, regardless of whether some of the remuneration was for a lawful purpose. The government does not have to prove patient financial loss or harm to programs to show a provider violated the AKS, and the AKS can be violated even if the provider rendered a medically necessary service. Because the AKS is so broad, and agencies and courts have interpreted it even more so, the anti-kickback provisions may inhibit certain otherwise innocuous conduct.[11] For this reason, safe harbors have been developed to protect certain practices that might otherwise cause the AKS to apply. OIG has exempted certain practices that might otherwise fall under the auspices of the AKS. In addition, special guidelines and fraud alerts are issued by the OIG from time to time for activities it believes may or may not implicate the AKS. Safe harbors apply only if the arrangement in question fulfills all the requirements outlined in the particular safe harbor. For example, some rental agreements, payment to employees, and investment in ambulatory surgical or endoscopy centers are allowed under safe harbors. Additional information on safe harbors can be reviewed on the OIG's website.[12]

Physician self-referral/Stark Laws

Physician self-referral occurs when a physician refers a patient to a medical entity in which he/she has

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a financial interest. The financial interest could be ownership, investment, or a structured compensation arrangement. Physician self-referral is viewed as a conflict of interest since the referring physician would financially benefit from the referral. Such arrangements are felt to lead to overutilization of health care services, thereby driving up the costs of health care, in addition to limiting competition by other health care providers.

Through the efforts of Representative Fortney Hillman "Pete" Stark, Jr. (D-CA) as chief congressional sponsor, Congress took the first step in passing a series of laws banning physician self-referrals with the adoption of the Ethics in Patient Referrals Act, (also known as the Stark I Bill), as part of the Omnibus Budget Reconciliation Act of 1989.[13] As enacted in 1989, the first Stark bill prohibited physician self-referrals to clinical labs under the Medicare program. The legislation was extensively amended in 1993 (now referred to as Stark II), to include additional health services considered to be susceptible to overutilization by physicians as a result of a conflict of financial interest, and to apply to Medicaid beneficiaries.[14] Stark II prohibits physicians from referring patients who are Medicare or Medicaid beneficiaries to entities with which the physician or an immediate family member has a financial relationship. The prohibited services are referred to as designated health services (DHS).

DHS include physical therapy services; clinical laboratory services; occupational therapy services; all radiology and other diagnostic services; radiation therapy services and supplies; durable medical equipment; enteral and parenteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospitalization services.[15] CMS issued final regulations pertaining to the Stark I and II that addressed the entire Stark regulatory scheme, given its complexity and evolution over the past two decades or so.[16] The intent of this rulemaking was to make the different areas of Stark that had been implemented over the years read as a unified whole.

There is a Stark III that speaks to certain physician-owned specialty hospitals beyond the scope of our discussion. Section 6001 of the Affordable Care Act of 2010 amended section 1877 of the Social Security Act to impose additional requirements for physician-owned hospitals to qualify for the whole hospital and rural provider exceptions. A physician-owned hospital is now generally prohibited from expanding facility capacity. However, a physician-owned hospital that qualifies as an applicable hospital or high-volume Medicaid facility may request an exception to the prohibition from the Secretary of HHS.[17]

The Stark Law is a strict liability law—proof of specific intent to violate the law is not required. There are civil penalties for a Stark violation. Claims submitted for services in violation of Stark will result in non-payment. If money is collected in violation of the self-referral law, that entity must refund the money paid. Improper claims may result in civil monetary penalties and exclusion from participation from Medicare and Medicaid programs. This penalty may not exceed $15,000 for each claim in violation of the law. Additionally, a civil penalty up to $100,000 applies to each circumvention scheme, such as cross-referral arrangements, when a physician or entity "knows or should know" that the arrangement has a principal purpose of assuring referrals by the physician to the entity. Alternatively, if a referral physician would directly violate the statute, the circumvention also violates the statute. There is a civil monetary penalty of three times the amount claimed and finally, any person who is subject to and fails to meet the reporting requirements faces a civil penalty not to exceed $10,000 per day in which reporting is required.[18] There are no criminal penalties for Stark violations.

There are certain exceptions, or safe harbors, in Stark with regard to certain financial arrangements. (A detailed listing of the individual exceptions is beyond the scope of our discussion.) Generally, these fall into three categories:

- exceptions applicable to both physician ownership or investment interests and compensation arrangements;
- exceptions for ownership or investment interest only; and
- exceptions for only compensation arrangements.

The Center for Medicare & Medicaid Services (CMS) is required to issue certain advisory opinions under Section 1877(g)(6) of the Social Security Act. An advisory opinion is an opinion by the government to provide guidance on whether a physician referral is prohibited by law for certain designated health services payable to an entity with which he/she (or an immediate family member) has a financial relationship. Advisory opinions are available to the general public through the CMS website as specified per 42 CFR §411.384. The opinions are very fact specific and are binding only on the requesting party in specific situations. No third parties are bound by, nor may they legally rely on, an advisory opinion.[19,20]

Conclusion

Health care fraud is rampant and being aggressively pursued by the government and law enforcement due to the billions of dollars of waste annually, in addition to the potentially negative impact on patients with regard to the safety and quality of health care delivery. The government applies various statutes when dealing with potential health care fraud situations. We have presented the three major laws pertaining to entities participating in

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the Medicare and Medicaid programs. These are the Federal False Claims Act, the Physician Self-Referral Law, and Federal Anti-kickback Statute.

These are extremely complex laws that require special legal expertise and opinion in order to prevent a health care institution and/or organization from falling into serious trouble through a violation. The compliance officer, whether new or seasoned, faces a daunting task of staying abreast of new legal developments in this area. Our review should provide a general overview and summary of the major laws and provide a firm starting point for work in the area of health care compliance. ■

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15. 42 U.S.C.A. § 1395nn(h)(6).
16. 72 Fed. Reg. 51012 (2007).
17. https://www.cms.gov/PhysicianSelfReferral/downloads/Section_6001_of_the_ACA.pdf
18. 42 U.S.C. § 1395nn(g)(1) through (5) (2006).
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Implementing continuous compliance improvement: A model for success

By Susan Acquisto, DNP(c), MS, RN, CHC

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The health care industry is facing increased scrutiny by the government, private insurers, law enforcement, and the community. With increased legislation surrounding fraud, abuse, and enforcement activities, it has become imperative for long-term care facilities to implement and maintain an effective compliance program. The program should be designed to utilize internal and external data to identify and prioritize risks and use a Continuous Quality Improvement (CQI) process to implement action plans. The facility's program should promote prevention, detection, and resolution of illegal and unethical conduct, and become part of the routine facility operations with benchmarks that demonstrate implementation and achievement of program goals.

Background

In the Federal Register publication of the Office of the Inspector General (OIG) Compliance Program Guidance for Nursing Facilities, the OIG published seven elements which should be included in an effective compliance program for all nursing facilities (see table 1 on page 40).[1] These seven elements offer voluntary guidance on how nursing facilities can best establish internal controls and prevent fraudulent activities.

Up until the passage of the 2010 Patient Protection and Affordable Care Act (PPACA),[2] a compliance program was completely voluntary in a nursing facility, and the OIG's recommendations were the only governmental guidelines demonstrating what an effective compliance program in a facility should incorporate. PPACA, however, mandates for the first time that all nursing facilities have in place a compliance program by March 2013. More specifically, section 6102 of PPACA outlines eight required components which must be included in a facility's compliance program (see table 2 on page 40), most of which directly resemble the seven elements supported by the OIG. As of yet, the Secretary of the Department of Health and Human Services (HHS) has not released a specific compliance model or implementation strategy to fulfill these requirements under PPACA.

Method

To implement and sustain the mandated compliance components under PPACA, the long-term care compliance model (shown in figure 1 on page 43) has been designed as a CQI process that provides the formal structure for the compliance program. The role of the interdisciplinary compliance team is to prevent, detect, and resolve illegal and unethical practices by utilizing and analyzing external and internal data, as shown on the model. From this data, risks to the compliance program are identified and subsequent action plans are developed, implemented, and evaluated for effectiveness in decreasing or mitigating risk. The data analysis results, action plans, and program compliance are communicated to all levels of staff, physicians, and vendors by the interdisciplinary compliance team. Trends and outcomes are reported to the Compliance Quality subcommittee, who

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in turn create dashboard quality reports with benchmarks to state and national standards.

The role of the Compliance Quality subcommittee is to support the compliance officer, Compliance committee, and the governing body/board of directors in the identification and analysis of quality-of-care indicators and to oversee the monitoring and evaluation of quality-of-care outcomes. It is the responsibility of the Compliance committee to determine appropriate strategies and approaches to promote compliance with program requirements and quality-of-care indicators, and to detect any potential violations through hotlines and other fraud reporting mechanisms. This information is reported directly to the governing body/board of directors, as shown by the flow of information in the model (see figure 1 on page 43).

Table 1: The Seven Elements

Seven elements of an effective compliance program recommended by the OIG Compliance Program Guidance for Nursing Facilities (2000)

- Implementing written policies, procedures and standard of conduct;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Enforcing standards through well publicized disciplinary guidelines;
- Conducting internal monitoring and auditing;
- Responding promptly to detected offenses and developing corrective action.

Table 2: Eight Compliance Components of PPACA

Eight components of a mandated compliance program under the Patient Protection and Affordable Care Act

- The organization must have established compliance standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under this Act.
- Specific individuals within high-level personnel of the organization must have been assigned overall responsibility to oversee compliance with such standards and procedures and have sufficient resources and authority to assure such compliance.
- The organization must have used due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under this Act.
- The organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents, such as by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required.
- The organization must have taken reasonable steps to achieve compliance with its standards, such as by utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under this Act by its employees and other agents and by having in place and publicizing a reporting system whereby employees and other agents could report violations by others within the organization without fear of retribution.
- The standards must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense.
- After an offense has been detected, the organization must have taken all reasonable steps to respond appropriately to the offense and to prevent further similar offenses, including any necessary modification to its pro- gram to prevent and detect criminal, civil, and administrative violations under this Act.
- The organization must periodically undertake reassessment of its compliance program to identify changes necessary to reflect changes within the organization and its facilities.

The long-term care model in figure 1 ultimately depicts the process of gathering external and internal data to help with the development, communication, and implementation of a compliance action plan. Additionally, the model's flow of information provides the opportunity for the compliance team and senior leadership to constantly revaluate the effectiveness of the program and make changes through the CQI process when needed.

An alternate long-term care compliance model (which was presented at HCCA's 2011 annual Compliance Institute by a panel of experts in the long-term care industry) highlights basic key components to sustaining an effective compliance program. These components emphasize communication and visibility of the program while building capacity through management, self-monitoring, performance improvement, and the utilization of interdisciplinary teams. Informing senior management of compliance issues while receiving their constant consultation and support, coupled with the implementation of meaningful standards and procedures, training, and risk management, are key to successfully sustaining this compliance model. The model's key components also include the utilization of proven tools, such as monitoring and reporting within the system, performance improvement, and adopting a system of quality improvement action planning. This gives the program the opportunity to grow and develop, enabling adaptation to changes in laws, regulations, and company policies and procedures.

A common theme between both models is the importance of using input from interdisciplinary teams to conduct internal monitoring and auditing in order to create/modify standards and procedures and maintain a system of quality improvement and risk management. The model in figure 1, however, expands on the flow of information and Compliance committee members and their roles. It also details which external and internal data the organization should reference when creating and implementing an effective compliance program.

For specific examples of effective compliance programs, organizations can also use OIG's Corporate Integrity Agreement (CIA) model. At HCCA's 2011 Compliance Institute, a best practice in long-term care compliance programs was presented using the model of a voluntary CIA. Certainly, the CIA model is comprehensive and inclusive of all the required elements of the OIG compliance guidance, because "CIAs have many common elements, but each one addresses the specific facts at issue and often attempts to accommodate and recognize many of the elements of preexisting voluntary compliance programs."[3] Regardless of size, location, or corporate structure, the company compliance program must be designed to operationalize the required elements. In order to provide structure to the program, it is useful to adapt a model that will meet the requirements, define communication lines, utilize a quality improvement process, and fit the size and budget of the organization. To view a complete list of the OIG's Corporate Integrity Agreements, visit http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp.

Result

Compliance programs that are hastily constructed and implemented without appropriate ongoing monitoring are ineffective and could result in greater risk or liability than if the facility had no program at all. A compliance program guides a facility's governing body (i.e., board of directors or trustees), chief executive officer (CEO), administrators, directors of nursing, physicians, and other health care professionals in the efficient management and operations of the organization. It is incumbent on the facility's governing body, staff, and administration to provide ethical leadership to the organization and to

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assure that adequate systems are in place to facilitate ethical and legal dissemination of information and guidance on applicable federal and state laws, regulations, and other requirements.

As illustrated in the compliance model in figure 1, developing an effective compliance program requires the participation of the following company team members: board members who have knowledge of health care; the CEO, compliance officer, legal counsel, and reimbursement specialists; the Finance, Billing, Operations, and Human Resources departments; and clinical discipline leaders (e.g., nursing and rehabilitation professionals). This interdisciplinary approach to compliance is just as important as the interdisciplinary approach taken in coordinating the residents' care in the facility. Because PPACA mandates that all long-term care facilities have a compliance program in operation by March 2013, small companies that do not have the expertise in-house may want to contract with external experts to review and provide input into the program, so that it includes the important and necessary components.

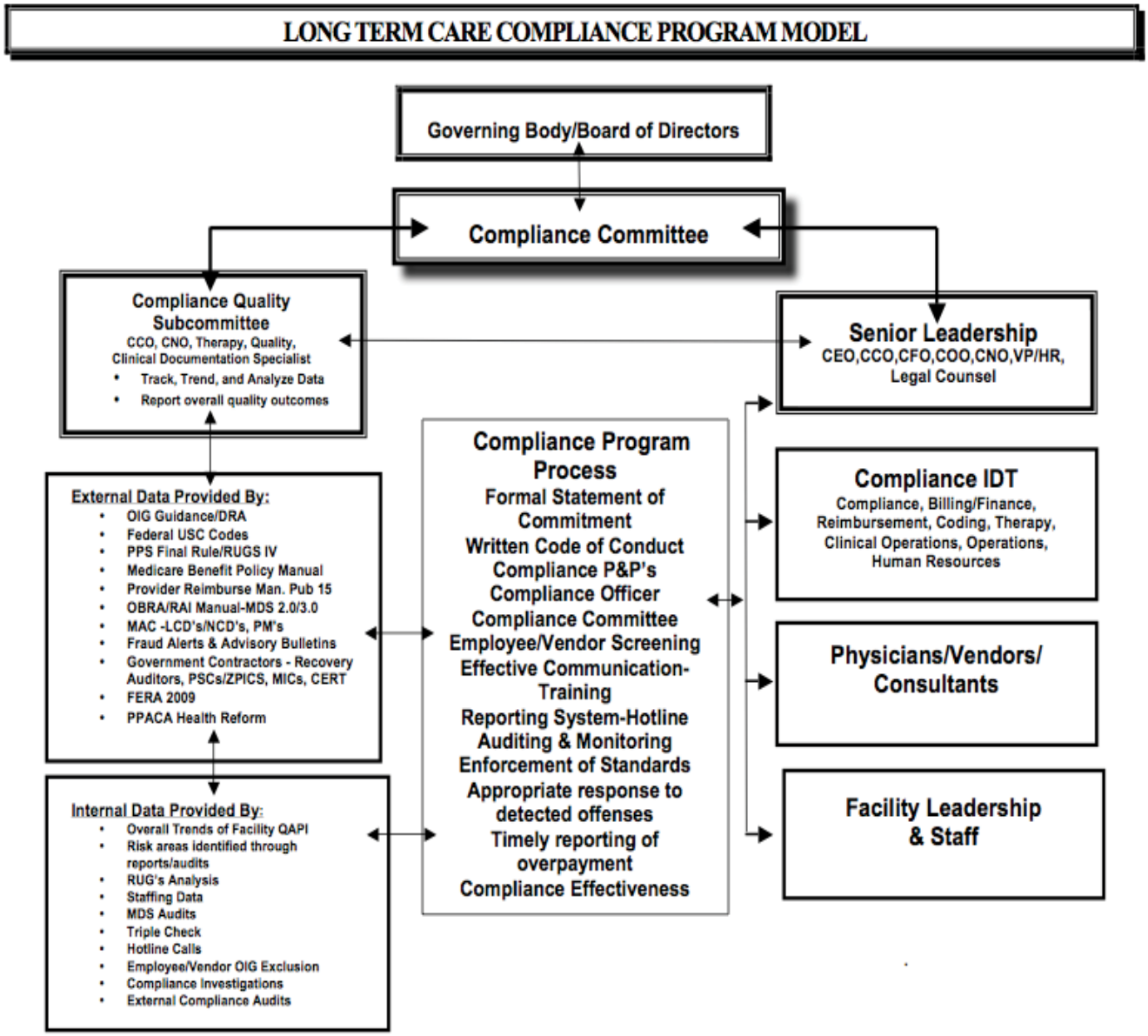
The processes of internal and external audits to identify risks, along with interdisciplinary communication and a culture of openness, are key to implementing the measures to control risk of violation of the compliance program. Under the False Claims Act, providers will be liable for offenses which they knew or should have known were fraudulent; therefore, it is expected that providers know the regulations by which they are governed in order to operate ethically and legally. Many long-term care facilities have developed compliance programs and are aware of penalties under the False Claims Act, but still find that some of their staff have knowledge deficits regarding Medicare rules and regulation, the Resident Assessment Instrument (RAI) process, billing and coding, and the principles of reimbursement. Consequently, in addition to training, each facility should have principle resources at their disposal for reference, such as the Medicare Benefit Policy Manual, MAC Billing Manual, OBRA regulations (Omnibus Budget Reconciliation Act, also known as the Nursing Home Reform Act of 1987), RAI Manual, Medicare Prospective Payment System (PPS) final rule regulations, and website addresses for their respective Medicaid Recovery Audit Contractor (RAC), and government auditors.

The facility compliance policy and procedure manual defines the compliance program according the OIG guidance and the laws and regulations listed in figure 1 that are related to fraud and abuse. The facility Medicare policy and procedure manual defines the facility-specific utilization and application of Medicare laws and regulations. The facility billing policy and procedure manual defines the facility-specific procedure on billing and submitting claims to their respective Medicare Administrative Contractor (MAC). Key regulations and references to assist your organization in developing policies, procedures, and training programs for the staff can be found in the model in figure 1 as well as in the detailed list shown in tables 3 and 4 on page 46.

In addition to these regulations, via their websites, the government sends communications to update providers about changes made. Important information is disseminated through program memorandums, such as Local Coverage/National Coverage Determinations, MAC newsletters, transmittals, OIG annual Work Plans, Special Fraud Alerts, and Advisory Opinions. It is well worth the time and effort to develop these essential policy and procedure manuals to guide and direct the staff practice.

One person alone cannot track, interpret, and implement all of these regulations and continual updates; thus, it is very important to have experts or team members responsible for specific areas in the development, implementation,

Figure 1: Flow Chart for Compliance Program



and monitoring of the compliance program. When the compliance team works toward a common goal by identifying compliance issues through external and internal data analysis, the task is not so daunting; regulatory update responsibilities are divided among staff from Reimbursement, Finance, Compliance, and Clinical Operations. As a result, team members learn from one another and can collectively interpret and make policies and develop comprehensive training for staff. Monitoring systems should be developed to assess if facility staff practice complies with written policies and procedures.

Quality assessments

According to the HHS OIG, the following areas of quality are assessed, monitored, and evaluated on a continual basis; therefore, it is essential that these specific provisions are divided up among your interdisciplinary compliance team for quality assurance and included in your nursing facility's compliance program.[4]

Staffing patterns

To evaluate that sufficient staff and competency exist to meet the

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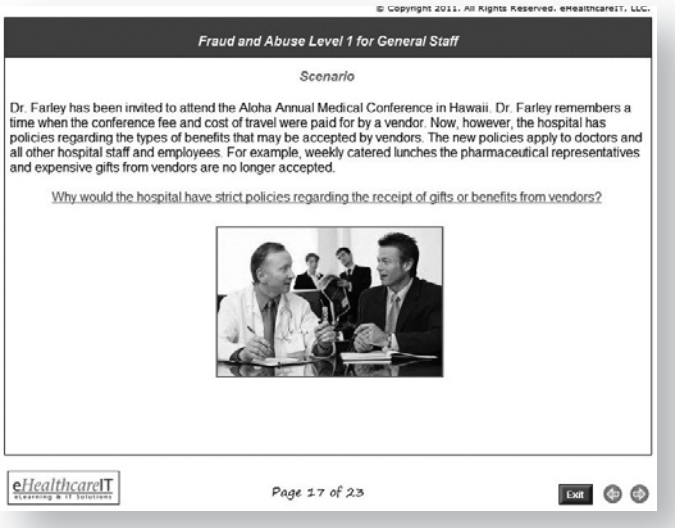

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acuity needs of the residents, staffing patterns are assessed regularly. Staffing is reviewed by analyzing internal reports for variances to budgeted staff. Assessment includes resident case-mix, staff skill levels, staff-to-resident ratios, staff turnover, staff schedules, and adverse events (e.g., falls).

To comply with the assessment standards of the OIG, staffing data should be reviewed by the facility Quality Assurance and Performance Improvement (QAPI) committee on a monthly basis. The committee should identify patterns or trends that may be correlated to staffing and address these through action plans. A pitfall to watch for in the calculation of hours per patient day (hppd) in a company's payroll system is the ability to capture direct care hours when a manager performs resident care. If the payroll system cannot discern when a nurse manager works the shift as a care provider with a resident assignment, those hours are missed in the hppd calculation, due to his/her employee management code in the system.

Comprehensive care plans

Comprehensive care planning includes all interdisciplinary team (IDT) members, complete assessments performed prior to meeting, open lines of communication with direct care providers, and IDT inclusion of the resident and resident's family. The documentation of these meetings includes length and content of each meeting and includes the attending physician's review of the care plan.

To meet these standards set by the OIG, open lines of communication and opportunities for the resident, resident's family, and staff input into the care planning process should occur during a Walking Rounds (WR) process, completed on admission and on a regularly scheduled basis, no less than quarterly. Communication of the scheduled IDT WR, with an invitation to the resident's family or responsible party to participate, supports a comprehensive care planning process. Care plans are reviewed during the IDT WR process and determinations for interventions/modifications to impact positive functional change are identified. The process assists in identification, appropriate communication, and accurate care plan documentation in the medical record when a patient's change of condition is observed.

Medication management

Pharmacy and nursing procedures are reviewed, revised, and monitored to ensure accurate acquiring, receiving, dispensing, and administering of all drugs and biologicals to meet the needs of each resident. The goals of proper medication management processes are to advance patient safety, minimize adverse drug interactions, and ensure that irregularities in a resident's drug regimen are promptly discovered and addressed.

To contribute to the successful implementation of these OIG standards, the pharmacist's Drug Regimen Review (DRR), medication pass audits, mock surveys, occurrence reports, and staff communication are important data elements to consider. These elements provide important information to be followed up by the facility director of nursing and pharmacist with reports to QAPI for ongoing monitoring, identification of trends, implementation, and evaluation of the medication management systems.

Another best practice is to assess medication administration competencies of the licensed nurses upon hire and at least annually thereafter by the consultant pharmacist, nursing/pharmacy liaison, registered nurse director of staff development, or nursing administration.

Use of psychotropic medications

Care providers are educated regarding appropriate monitoring and documentation practices and action required for drug regimen reviews. Resident care plans incorporate an assessment of the resident's medical, nursing, mental, and psychosocial needs,

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including the need for psychotropic medications for a specific medical condition. The attending physician, medical director, and consultant pharmacist (along with other care providers) collaborate to analyze the outcomes of care by using the results of the DRR, progress notes, and monitoring of the resident's behaviors.

On a monthly basis, facilities should track and manage utilization of antipsychotics for all patients through QAPI to meet the standards set by the OIG.

The data from the DRR, progress notes, and behavior monitoring plans are utilized to verify that alternative measures are discussed and implemented, as appropriate, prior to the introduction of an antipsychotic.

Promoting resident safety

All allegations or suspected abuse involving a resident, staff, visitor, or volunteer should be properly managed, documented, and reported to ensure individual safety and to meet all state and federal regulatory requirements.

To comply with these standards, the Abuse Prevention, Intervention, Investigation, and Reporting policy should be implemented by the administrator and director of nursing with oversight provided by the Quality Assurance and Improvement committee. Policies and procedures, staff education, and understanding of appropriate practices specific to resident safety and abuse can be reviewed during annual mock surveys and staff meetings/trainings performed at least quarterly.

Table 3: Key Regulations, References, and Resources

Key regulations and references to use when developing policies, procedures and training programs

- OIG Guidance 2000, 2008/Deficit Reduction Act (DRA 2005)
- Federal United States Codes (USC) to include: False Claims Act, Anti-kickback Law, Stark I & II, Safe Harbor Laws, and Federal Exclusions and Sentencing Guidelines
- Prospective Payment System (PPS) Final Rule/RUGS IV
- Medicare Benefit Policy Manual
- Provider Reimburse Manual, Pub 15
- Medicare Administrative Contractor (MAC) Billing Manual
- Omnibus Budget Reconciliation Act (OBRA)/ Resident Assessment Manual (RAI)-MDS 3.0
- MAC –Local Coverage Determination's/National Coverage Determination's, (LCD/NCD) Program Memorandums (PMs)
- Fraud Alerts & Advisory Bulletins
- Government Contractors-Recovery Auditors, Program Safeguard Contractors (PSCs)/ Zone Program Integrity Contractors (ZPICS,) Medicare Integrity Contractors(MICs), Comprehensive Error Rate Testing (CERT)
- Fraud Enforcement Recovery Act of 2009 (FERA 2009)
- Patient Protection and Affordable Care Act of 2010

Table 4: Key Resources

Organization	Resource
OIG Original Compliance Program Guidance for Skilled Nursing Facilities (2000)	http://www.oig.hhs.gov/authorities/docs/cpgnf.pdf
OIG Supplemental Compliance Program Guidance for Skilled Nursing Facilities (2008)	http://oig.hhs.gov/compliance/compliance-guidance/docs/complianceguidance/nhg_fr.pdf
Text of the Patient Protection and Affordable Care Act (PPACA)	http://www.healthcare.gov/law/full/index.html
OIG's list of Corporate Integrity Agreements	http://oig.hhs.gov/compliance/corporate-integrity-agreements/cia-documents.asp.
False Claims Act	http://uscode.house.gov/download/pls/31C37.txt

Benefits of a compliance program

Once a nursing facility has successfully implemented its compliance program, its organization will not only fulfill its legal duty to ensure that it is not submitting false or inaccurate claims to government and private payers, but the compliance program will also assist in the following.

Identifying weaknesses

An effective compliance program identifies weaknesses in internal systems and management, thereby increasing productivity and safety within the organization. An effective compliance program must have a Compliance committee that enforces policies; provides assistance in employee education; analyzes legal requirements of the organization; develops dashboards for tracking, analyzing, and reporting data involving resident/customer satisfaction, staffing, and nursing hours, care plans, etc.; and monitors internal and external audits and investigations for purposes of identifying deficiencies and implementing corrective actions. Developing these kinds of policies provides strong guidance to the organization that enables management to pick up patterns of bad behavior, misconduct, or non-productive activity and identifies where the facility falls short of established benchmarks, all of which contribute to a culture of weak compliance.

Demonstrating commitment to honest and responsible conduct

An effective corporate compliance program creates standards and practices for which an organization, its board members, and staff are held accountable. This demonstrates to the employees and to the community the facility's commitment to honest and responsible provider and corporate conduct. It is important that all members of the organization, regardless of rank, are held accountable to all standards, policies, and procedures. The compliance program will not prevent all wrongful activity, but it shows the facility and the community the standards to which the organization is held. Furthermore, a compliance and ethics program demonstrates the organization's commitment to not only uphold the law, but to a strong commitment to practicing ethical, moral behavior.[5]

Providing guidelines relating to fraud and abuse

The compliance program needs to outline policies and procedures regarding employee/contractor relationships as well as penalties if a violation occurs. It is strongly advised that the organization conduct periodic trainings, post information, distribute leaflets, and/or provide compliance videos which teach all staff, contractors, vendors, and business associates how to legally and properly conduct relationships with the facility to avoid fraud and abuse allegations.

Identifying and preventing criminal and unethical conduct

By educating staff on accepted conduct, the facility reduces the likelihood of members in the organization breaking the law or committing a crime in the first place. The compliance policy should lay out accepted behavior and punitive actions if any policy is violated.

The U.S. Federal Sentencing Guidelines offers reprieve for any organization convicted of a crime that has an effective compliance program in place. Although having an effective compliance program will not eliminate the crime, the Sentencing Guidelines state that if an offense occurred at the time the organization had an effective compliance program established, it will lower the organization's overall culpability/liability score when determining the sentence.[6]

Creating a centralized information source

The field of health care legislation is one with no boundaries; new rules, laws, and regulations are created every year. All facilities are expected to be aware and follow health care regulations and other program directives related to fraud and abuse issues. In

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addition to legislation are Joint Commission standards and an array of Medicare auditors who issue and enforce guidelines. It is virtually impossible for all staff to continue providing care to residents and, at the same time, adequately stay current on new laws and regulations. Therefore, the facility's Compliance committee must maintain current information in the compliance manual, conduct trainings on new material, distribute leaflets, and post useful information to relieve the burden of staying current for staff. A compliance program with accompanied training sessions is a great way to keep staff updated on identified risk areas in the organization and in the industry. Importantly, ensure your staff knows where to find the compliance manual within your organization, and make it readily accessible to anyone who wishes to read it. The Compliance department should be the central hub for distributing regulatory information.

Encouraging employees to report potential problems

Through the compliance program, a system of reporting should be established. Employees should be encouraged to report any activity that violates the law, organizational policies, or the company's code of conduct and ethics, and all cases of reporting must be treated seriously, timely, and fairly by the compliance officer. Staff should be given the option to make reports anonymously or in confidence, and there should be multiple facets through which an employee may report. For example, reports may be made through a compliance hotline, through a supervisor/manager, or by writing to a compliance address. As a result, employees will be encouraged to uphold the rules, knowing every report will be taken seriously and handled fairly.

Developing investigation procedures for alleged misconduct

The prompt, thorough investigation of alleged misconduct by corporate officers, administration, employees, independent contractors, physicians, physician extenders, other health care professionals, and consultants is a must. With an effective compliance program, the facility will have time to correct any problems before they grow out of control and are discovered by external auditing agencies, thereby reducing risk of penalty to the organization. Regular monitoring and internal auditing provide early identification of program or operational weaknesses.[5]

The cost of an investigation and litigation are extremely high; therefore, the cost in time and resources needed to implement and sustain a compliance program are well worth it. Take, for example, the case of a facility that has no compliance program and therefore, no standardized training schedules. Incidentally, a newer staff member naively initiates the use of a psychotropic medication to a resident without getting consent from the resident first, because the staff member was never educated on a policy the facility never bothered to write down. If an investigation were to subsequently occur, it would not only lead to the obvious costs the facility would pay an attorney, but it could potentially lead to negative publicity for the organization, diversion of facility resources to take on the investigation/ligation, or cause undue stress to employees who may need to be questioned or take on additional work because of the added efforts directed to the investigation.

Initiating immediate and appropriate corrective action

It is not only important to establish policies and procedures in a compliance program, but an organization also must include penalties and/or corrective action for violating these provisions. Once these provisions have been established, it's vital that all members of the organization are held to them. For example, whether a certified nursing assistant or the facility's director of nursing is accused of falsifying medical records, both members of the organization must be treated the same in this situation. By establishing corrective action in

advance, the facility will not need to waste time coming up with an appropriate plan when a violation has occurred; rather, they can spend more time and resources to counsel the employee or provide assistance in the investigation where needed.

OIG recognizes that the implementation of a compliance program may not entirely eliminate fraud and abuse from the facility/company; however, the serious effort in implementation of this program to comply with the applicable federal and state laws significantly reduces the risk of unlawful or improper conduct.[7]

Conclusion

Implementation of an effective compliance program with risk control indicators requires an integrated approach to implementation and enforcement of policies and procedures, training, and auditing. This model requires the interdisciplinary team approach with open lines of communication with all staff and the board of directors, because it is imperative in measuring effectiveness and maintaining a low probability of risk events. By using a long-term care compliance model, such as the one shown in figure 1, a nursing facility can take steps in the right direction to establish and sustain an effective program, and by doing so, their organization can reap invaluable benefits. ■

1. 65 Fed Reg 14289 (Mar. 16, 2000)
2. Patient Protection and Affordable Care Act, Public Law 11-148, 124 STAT 119 (Mar. 23, 2010)
3. Available at http://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp
4. OIG Supplemental Compliance Program Guidance for Nursing Facilities, 73 Fed Reg 56832 – 56848 (Sept. 30, 2008)
5. Office of the Inspector General of the U.S. Department of Health and Human Services and The American Health Lawyers Association: Corporate Responsibility and Corporate Compliance: A Resource for Health Care Boards of Directors. Available at http://oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf
6. Unites States Sentencing Commission, Chapter Eight: Sentencing of Organizations, (Nov. 1, 2010).
7. Publication of the OIG Compliance Program Guidance for Nursing Facilities, 65 Fed Reg 14289 (Mar. 16, 2000).

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On mentoring

By John E. Steiner, Jr., Esq. and Alan Peterson, Hon DBA

Editor's note: John Steiner is Chief Compliance Officer with Cancer Treatment Centers of America, Inc. in Schaumburg, Illinois. Dr. Alan Peterson is a Managing Director with Robinwood Consulting LLC in Chicago. Contact John at John.Steiner@ctca-hope.com and Alan at apeterson@rwdconsulting.com.

This is the first part of a two-part article on mentoring published in **Compliance Today**. *The authors combine their individual perspectives, rather extensive experiences, and current thoughts on mentoring. Thus, this article reflects both a variety of health care workplace principles and specific points related to mentoring and leadership, with some discussion of topics of particular value to health care compliance professionals.*

As often occurs in the U.S., our health care system is challenged today in several ways. Uncertainty is the rule. There is neither a widely accepted consensus on what our health care system should be nor agreement on how to pay for health care services. Thus, as with any challenge, leadership, energy, and creativity are essential elements for both individual and organizational successes. And, as with most advances, we typically build on the successful efforts of others. Often, that progress is based on sound mentoring of persons, regardless of age or specific experience.

Mentoring is a recognized part of the value of leadership. We modestly favor informal mentoring methods and urge careful planning before fully embracing formal mentoring programs. At a minimum, our suggestions should help conserve financial capital and help focus the allocation of organizational resources (both human and financial) most effectively. This point about mentoring is especially important during times of tight cash flow or overall reductions in health care payments, now more than ever.

Brief mentoring history

Mentoring is not a new idea; mentoring is simply a key facet of leadership. Mentoring is not a recent invention of today's human relations experts, of scholars, or of direct line supervisors themselves. Rather, mentoring has been with mankind for thousands of years. Today's informed health care compliance professionals and others correctly recognize mentoring as part of leadership.

According to *Oxford Dictionaries*: **Mentor** – *noun*: an experienced and trusted adviser. Origin: mid-18th century: via French and Latin from Greek *Mentor*, the name of the adviser of the young Telemachus in Homer's *Odyssey*.[1]

In addition, according to Oxford, "The word also is used to mean a trusted counselor or teacher, especially in occupational settings."

In most organizations, it is noteworthy that mentoring occurs whether or not the mentoring activity is included in job specifications of leadership positions, in organizational training, or otherwise in policy. Mentoring also occurs whether or not there is any formal investment by the organization in mentoring or whether the organization's leaders consider mentoring part of their roles. Mentoring happens.

Key attributes of leadership including mentoring activity include:

- Integrity
- Communicating vision
- Strategic management
- Wisdom
- Training
- Emotional intelligence
- Credibility
- Encouraging supervision
- Humor
- Initiative
- Self-awareness
- Confidence

For an amusing treatment by Hollywood of mentoring, especially in one family (largely

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for their butler), observe **My Man Godfrey**, a 1936 film and winner of six Academy Award nominations.[2]

Today's health care leadership must combine the ability to secure and allocate resources (e.g., time, skills, capital, etc.). Likewise, leaders must assure that appropriate persons have opportunities to use those resources to do what appears best and what, hopefully, turns out to be good for the organization as well as for the community; in other words, "doing the right things," usually through thoughtful collaboration, including organizational leadership and mentor-protégé activities.

These are truths for health care organizations in particular.

Formal vs. informal

Health care professionals may think of mentoring in terms of their personal experiences in health care training. A well-known medical training expression is, "See one, do one, teach one." That expression captures a training method that may be both part formal and part informal, depending on the setting as well as depending on the leader, mentor, protégé, and trainee relationships.

Mentoring in an organization is a bit like water; it will seek some level on its own. It may be noteworthy that in some settings, we believe that *no formal mentoring often is better than a bad formal mentoring system or program*, with the related risks.

Many efforts at creating what leaders refer to as a "formal mentoring system" or a formal "program" are poorly planned and poorly executed. Thus, those systems or programs encounter problems due to failure to follow proper design or implementation processes, inadequate testing, and debugging. Inadequate budgets often plague new formal mentoring systems as well as hampering some informal mentoring approaches, and thus result in anemic efforts and unacceptable results. In turn, the sponsoring organization and its teams or departments must work quite hard to overcome the problems and achieve some reasonable measure of mentoring success. At times, this effort at repair does achieve a fair result.

Informal mentoring approaches are a good deal less structured and appear less "driven" than a widespread formal mentoring program. Informal mentoring approaches are characterized by longer corporate or government mentoring life as an element of leadership (i.e., sustainability). Such approaches may start with somewhat lower expectations but, ideally, include a sharp focus on those expectations. In turn, informal mentoring may lead to better execution of mentoring improvements based on personal collaboration—mentor and protégé to benefit all.

Often, informally mentored employees have a stronger, personal feeling that senior organizational leadership cares about those being mentored. That dynamic fosters greater willingness of protégés to become good mentors for others later in a protégé's organizational life. Ultimately, this effort builds stronger working relationships with fellow employees in general, and especially good identification with the organization's overall mission and values. This powerful sequence of activities usually contributes to improved patient experiences and employee satisfaction in health care.

Some basic, but less tangible, differences between informal and formal mentoring programs include:

- Informal mentoring lacks the somewhat considerable corporate reporting and "check-the-box" administrative tasks (or mentality) and related so-called "metrics" of mandatory broad-based formal mentoring programs.
- Informal mentoring tends to be easier for mentors to achieve reasonable "personal buy-in"

as well as an enthusiasm for their mentoring tasks and clear enthusiasm for favorable results.
- Informal mentoring has a lower risk of failure, in part due to those fewer administrative tasks, less formal or mechanical reporting, more flexible time allocations, more realistic expectations, etc.

A well done informal mentoring program, with strong top leadership backing (tone-at-the-top) offers these benefits, among others:

- Informal mentoring can be aligned with other organization leadership objectives or policies (e.g., delegated accountability, effective regulatory compliance, excellence in quality assurance, integrity, etc.).
- Informal mentoring training, even if temporary, often is easier and may be more effective for leaders, mentors, and protégés than a more rigid, formal program.
- Organizational training objectives related to personal behavior changes often are easier to achieve through informal mentoring.

Other important mentoring considerations

Another way to consider health care mentoring is good to know, because the health care industry in the U.S. continues to grow quite vigorously, despite the current, economic downturn. Those with substantial health care industry provider experience would tell you that they received relatively "heavy-duty" mentoring of the more informal character throughout their health care provider careers. It's how they nicely learned both important and less important facets of their jobs. We have heard this from many people.

Those experienced health care persons in provider settings considered it all part of the "trade"—learning from their leaders. Although it may sometimes be inconsistent, that type of provider mentoring is prevalent and quite successful to an extent.

But, for most employee groups (but possibly excluding health care providers) mentors often will not be the direct line, next-level supervisor of the protégé (in a command and control sense), so similar leader-to-protégé training may not happen. Also, absent that direct relationship, mentors must be careful not to aggressively interfere with the direct line supervisor's responsibilities; rather, mentor attention to a protégé's challenges should generally involve constructive collaboration, but not line management interference.

In the U.S., along with growth of better care for a larger population as well as longer lives of that population, has come huge increases in numbers of health care employees: (1) at regulatory government entities that employ many; plus (2) at payers as employers. Those two groups find themselves seeking or being persistent about proof, proof, and more proof of the prudence, appropriateness, and safety of their parts of our nation's health care. Moreover, government regulations are often unclear as well as a bit excessive. Then, like good managers of health care would be expected to seek, the subject of predictability has most recently joined the ranks of health care high-priority desirability with related (hopefully lower) costs than many alternatives.

With regard to mentoring, it is appropriate to point out characteristics common to the two large non-provider groups: government regulatory personnel and payer personnel. Those groups probably have more limited experience with mentoring than do most health care provider organizations. Thus, mentoring as part of leadership in both government and payer groups should be different. All, of course, can use informal style advantages.

Various health care regulatory requirements and associated liabilities (both individual and organizational) have increased the emphasis on sound compliance efforts within organizations. To a certain extent, those efforts

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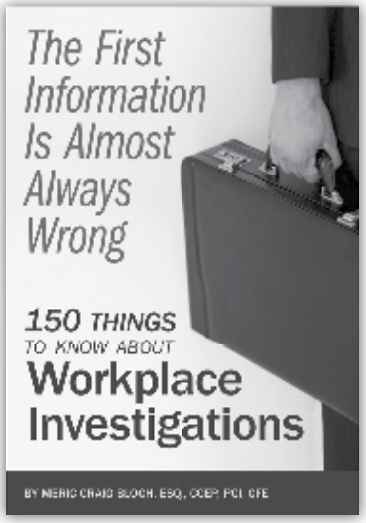

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require reasonably consistent (or "standardized") approaches towards regulatory compliance. Stated another way, there is a premium on "predictability" of the workforces' compliant behaviors. But, standardization in health care can be carried to an extreme, can become a "crutch" for less care vs. thoughtful treatment, can void other sound health care training, etc.

Good mentoring and training can help employee behavior change to increase overall predictability of desirable conduct. Mentoring can help protégés continue to understand the need for excellent care, including relevant standardization, as well as the limits of standardization; and can aid faster personal development in medical learning and science learning for protégés—to the advantage of patients as well as leaders.

In our experience with providers, such learning-through-training helped by provider mentoring is constantly going on, an advantage less so with other groups (i.e., government and other payers).

A few comments and suggestions

There has been a good deal of research, experimentation, and publishing on the subject of mentoring. Generally speaking, many views of mentoring are quite favorable. Mentoring also "sounds good" to most constituencies.

But as a term, "mentoring" has many diverse uses and meanings, particularly in the work setting. In health care today, much good research work on mentoring remains to be completed successfully, ratified, and turned to effective health care use.

Health care organizations should follow sound system processes for any mentoring improvement changes and adopt practical measures of the outcomes of those processes. These processes, which we refer to here, are generally accepted, widely used, and well written-on; they can be summarized as:

- Careful design of any health care mentoring improvement (preliminary design and final design);
- Careful installation and implementation of the mentoring improvement; appropriate testing, check out, and integration, as well as debugging of the mentoring improvement; and
- Effective use of the mentoring improvement, importantly including tests of use.

Following are a few of our general observations on mentoring and on an organization's approach to internal research.

More research

We believe that many conclusions on mentoring have been reached without use of appropriate "control group" tests or similar criteria. This raises a practical question: How should an organization design and use a control group for conducting its mentoring research? The answer is, "With care."

The long-term record on successful design and implementation of formal mentoring programs is inconsistent, and it should be recognized that certain mentoring designs may not obtain more than a short or temporary surge of limited employee goodwill. Significantly, an overall leadership shortfall in general cannot easily be sorted out from the more narrow use of the term "mentoring." Again, organizational care is important. For example, our trade information is that few mentoring formal programs survive six years.

Our nations' health care professionals and academic advisors must research and test a good deal more on broadly applied, across-the-board mentoring efforts. This is especially true in health care where industry coverage and health care itself continue to grow rapidly.

Good leadership and good mentoring in health care

As indicated, good mentoring should be an integral component of any health care leadership and vice-versa. Many leaders in health

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care already do put forth a lot of mentoring within their organizations. In the area of health care compliance, for example, the critical steps for effective compliance include senior leadership support. That support, in turn, allows sound design, installation and implementation, testing, and downstream administration of the compliance in an organization's mentoring program in a matrix sense, among other things.

Mentoring "implementation," in particular, requires effective delegation of accountability across an organization. A frequently asked question is: "Who is accountable for what, and when?" This is an example of where mentoring can come into play and benefit an organization, its employees, customers, and communities; especially in heavily matrixed, heavily regulated, complex, and dynamic organizational environments. Leaders who agree to mentor in such an environment must have experience.

In turn, protégées must have appropriate time, tools, and leadership support to apply the lessons suggested by the mentors. Thus, the role of a leader becomes particularly important and relevant in helping the mentors, as well as helping employees.

More visible examples of mentoring collaboration can include useful delegation of protégé responsibility to specific committees' tasks or projects that apply across the organization, with sound periodic oversight and guidance by the leaders and by sound use of mentors. Typically, those in compliance leadership roles can "brief" others on the relevance of the compliance risk areas. Those same leaders may guide mentors and protégées in thinking about their compliance related roles and responsibilities, but they should not give the protégés all of the review answers before field assessment is near completion or give canned answers too early in the task. Additionally, mentoring protégées can be encouraged to engage others within the organization about the "goodness" of the leader's work, the "goodness" of training, etc.—as experienced.

The depth of engagement among protégés, mentors, and relevant leaders can include process reviews, areas involving audits, training programs, and the like. Both the protégée and others in the organization should understand why the special work being discussed here is being undertaken in the organization. In the compliance context, there generally are three iterative steps: Does the work pertain to (1) design itself, (2) implementation, or (3) administration and successful use of the effort to learn or improve something—each with appropriate objectives? When the objectives of the mentoring have been reasonably established, the mentor, protégés, and others involved can carry-on and help accomplish good things for leaders as well as the organization and for the protégés themselves.

Again, there can be a loose analogy here to our prior reference in the medical training expression, widely known as "See one, do one, teach one" (notice the "balance" with training). Frankly, that reference should be one of the best simple models to be applied today by health care organizations, where appropriate.

We believe that most compliance exposure to a broad array of risks relates to a lack of focus and, in some cases, insufficient time for employees to be introduced, to learn, and to apply the regulatory compliance rules. In turn, most non-compliant conduct in health care is also subject to civil sanctions (that part of the iceberg below the waterline—where a lot of compliance risk exists). Such sanctions are linked to a standard of expected behavior (i.e., the "knew or should have known standard" briefly mentioned later herein); or, for example, under the Health Insurance Portability and Accountability Act (HIPAA), the "willful neglect" standard. And,

Continued on page 58

company or government policies must be trained on as well. In this setting, mentoring and leadership merge, because both activities are designed to help others, to help the organization deliver health care services to patients, and to avoid compliance challenges, among other specific objectives.

A reference to a legal standard of non-compliance does have considerable relevance for mentoring within health care. In our experience, the legal or regulatory standards point helps both a mentor and a protégée to "connect some dots" of overriding compliance in the presence of somewhat unique health care issues. In other words, for this article, mentoring as a part of leadership attributes should relate to something fairly tangible to the organization and possibly for compliance—to the organization's mission, its patients, its customers, and its fellow healthcare colleagues—all in a helpful style. Thus, the examples illustrate the importance of crafting and carrying out a mentoring program designed to help protégés and the entire organization as well.

Exchange of ideas

There is another, critical element of effective mentoring of relevance in the compliance arena. That element is linked to a common human trait. For the most part, people in a relatively free country like to be asked to give opinions. The related corollary in compliance is that there is no such thing as an uninformed compliance question. In other words, it is fine and expected for protégé individuals to ask questions of leaders as well as mentors, seek advice, voice their opinions, as well as receive opinions. Thus, the leader of an effective health care compliance program must instill this open understanding and transparency in others in the organization.

This knowledgeable leader-mentor effort can enhance the design phase of mentoring improvement and the culture within an organization by helping individuals raise appropriate questions or concerns for resolution.

There are some important differences of mentoring in health care organizations, compared with other mentoring settings.

Human life at all ages can be an issue, one which makes adding or changing mentoring for an organization quite sensitive and complex procedurally and behaviorally. This is a fact that is particularly important, along with a fact that major federal and state regulations too often conflict with (or appear to conflict with) ethical, organizational, and personal standards. Carefully consider the views of physicians, surgeons, technical support persons, therapists, etc. about regulation. These people tell story after story of required or indirectly caused health care regulatory treatment with which they had personal—e.g., ethical—disagreement. They should be thoughtfully heard in the design of the mentoring improvement phase.

And, the insurers and payers in the health care and human life area ask, "Who gets?" "Who pays?" Mentors can assist the communication of answers.

Huge federal and state funding have attendant health care regulatory emphasis (i.e., "following the money") and involve a difference or uniqueness with much of the rest of our relatively free economy, especially the private company side). The federal and state regulatory oversight of health care itself is enormous and detailed. Moreover, great personal liability risks exist in the delivery as well as the administration of health care, a major complexity in health care mentoring.

Mentoring can go badly if personalities are mismatched, and a bad experience can have lasting consequences for both the mentor and the protégé. Organizations need to be alert for early signs of trouble, such as intimidation, sabotage, manipulation, or jealousy.[3]

More on mentoring in health care

Many special uniquenesses must be considered when mentoring in the health care world. One central uniqueness is the focus on the patient from many perspectives. Most importantly again, there remains the fairly direct heath care involvement with human life—a precious asset involving care by our skilled professionals, which many providers believe is an issue not fully understood by health care regulators.

To use an analogy, fighter bomber pilots, aircraft pilots, and astronauts may feel they are different and significant. We deal with them as "special." Consider nurses, surgeons, doctors, payer billing experts, specialists, government leaders, etc. and their roles in health care mentoring. They too, are "special." Moreover, the US health care system significantly needs its valuable professional people and teams. Mentoring should also work on helping with the retention of experts and valuable personnel and on avoiding losses from turnover.

Summary

As indicated, today the US health care world is facing huge uncertainties. There is no national consensus on what health care should be delivered, or what can be afforded in a regulatory or public sense. The tensions between those two choices represent an important opportunity for leadership and mentoring. Good leadership remains a paramount need in health care. If strong mentoring can help health care leadership, great. If not, we need to identify what can assist health care leadership and move toward trying and accomplishing a significant solution in a timely way. ■

1. OxfordUniversity Press, Copyright © 2011 Oxford University Press. All rights reserved.
2. **My Man Godfrey**.1936. Directed by Gregory La Cava, screenplay written by Morrie Ryskind, based on "1101 Park Avenue," a short story by Eric Hatch. The film stars William Powell and Carole Lombard. Available from Legend Films on DVD.
3. Dawn E. Chandler, Lillian Eby, and Stacy E. McManus: "When Mentoring Goes Bad." *Wall Street Journal*, May 24, 2010. Available at http://online.wsj.com/article/SB10001424052748703699204575016920463719744.html

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