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Improving quality of care: OIG releases report on nursing home compliance programs

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The transformation of the United States health care system from a volume-based system to a value-based system is not a new concept. The government has made clear that the shift to a value-based system is a priority and will become a reality in the near future. Although organizations know that quality is a top priority for the government, many grapple with how to improve quality in light of the new government mandates. On April 22, 2009, the US Department of Health and Human Services, Office of Inspector General (OIG) released a report[1] finding nursing home corporations under quality-of-care Corporate Integrity Agreements (CIAs) enhanced their quality-of-care structures and processes by integrating quality into their compliance programs. This report supports the fact that quality can be improved by integrating it into compliance.

The OIG's report examined 15 nursing home corporations that were under quality-of-care CIAs for at least one year as of December 2006. A quality-of-care CIA generally lasts between three to five years and includes the following requirements:

- An independent quality monitor selected by the OIG;
- A designated compliance officer and a corporate-level Quality Assessment and Assurance (QAA) committee;
- An internal quality-of-care monitoring system;
- A confidential disclosure program (e.g., hotline);
- Written standards, policies, and procedures;
- Screening of prospective employees and contractors;
- Competency-based employee training programs; and
- Submission of status reports and certain events reports to the OIG and quality monitor.

Notably, these requirements are remarkably similar to the elements of an effective corporate compliance program.

To meet CIA requirements, the 15 corporations surveyed by the OIG created or expanded their compliance infrastructure to integrate quality of care. Specifically, each corporation reported having a quality compliance program led by a designated quality compliance officer, with each compliance officer having sufficient authority and support to perform his or her expanded duties.

Additionally, not unlike an effective compliance committee generally, the QAA committees, required by the CIAs, were structured with their membership and responsibilities integrated into the corporate structure, with written policies and procedures developed that specifically addressed quality-of-care issues.

Moreover, as part of their quality compliance infrastructures, the corporations developed internal monitoring systems to identify quality-of-care problems and monitor progress. Assessment tools developed or adopted by the corporations to assess compliance risks were expanded to include quality-of-care risks, such as the Centers for Medicare and Medicaid Services (CMS) Quality Indicators/Quality Measures, state survey deficiency reports, mock surveys, satisfaction surveys, chart audits, staffing measures, and complaints. The corporations reported that quality issues identified through their internal monitoring systems prompted development of action plans to address the issues.

OIG concluded that the CIAs helped guide the development of standardized processes and quality systems, and facilitated communication with employees regarding the importance of quality—steps that were viewed positively as improving quality processes and structures. In short, the CIA-required integration of quality into compliance provided the push these corporations needed to institute concrete quality improvement initiatives.

OIG's conclusion that quality-of-care CIAs caused these 15 nursing home corporations to enhance quality-of-care structures and processes in their systems is important for all hospitals, nursing homes, and other providers who are subject to quality reporting by CMS. This study supports the fact that integrating quality into compliance improves overall

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quality processes and structures, a positive step that is likely to improve overall performance on quality targets.

Integration of quality into corporate compliance

The expansion or creation of an organization's compliance structure to integrate quality now can position all providers, not just nursing homes, to be prepared for the inevitable shift to value-based purchasing (VBP). VBP has not been implemented yet by Medicare, but in the Deficit Reduction Act of 2005 (DRA), Congress authorized the Secretary of Health and Human Services to develop a plan to implement VBP for Medicare Inpatient Prospective Payment System (IPPS) services for FY 2009. The plan was developed by CMS and submitted to Congress in November 2007. The VBP plan outlines the performance model and process for calculating incentive payments and would be phased in over a three-year period. The VBP plan would reward hospitals that improve quality performance as well as those that achieve high levels of performance. Incentive payments of 2% to 5% would depend on the hospital's performance rate. Although the VBP plan is not yet authorized, it has been included in many of the health reform proposals currently under consideration, and many private programs and several states already have instituted VBP initiatives.

The expansion or creation of an organization's compliance structure to integrate quality can also protect the organization from costly investigations or recoupment efforts by the government, based on quality failures. If the government discovers quality failures within an organization, the government may attack the quality issues using the False Claims Act (FCA). For example, in *Campbell ex rel. v. Redding Medical Center*,[2] the government accused Redding Medical Center (RMC) of allowing physicians to perform medically unnecessary cardiac procedures. The government alleged that RMC violated the FCA, because RMC provided medically unnecessary services and substandard invasive heart procedures. RMC's parent company agreed to pay $54 million to resolve the allegations.

If the government discovers quality failures within an organization, the government may impose a range of penalties for such quality violations, including repayment of improperly received reimbursement, imposition of severe financial penalties, criminal prosecution, or exclusion from federal health care programs. Because quality of care soon will be linked directly to the right to payment, quality can potentially be enforced under the FCA. Violation of the FCA can result in liability of three times the amount of damages the government sustained by paying the claims plus civil penalties of $5,500 to $11,000 per claim.[3]

The integration of quality processes and structures into the compliance program of complex organizations (e.g., hospital systems) requires a broad-based coordinated approach among administration, medical staff, nursing staff, risk managers, Utilization Review, the Quality department, the Compliance department, and legal counsel. Implementing such a broad-based approach may require significant restructuring of the various departments and processes within an organization, which can be challenging because quality traditionally has not been a focus of most organization's compliance concerns.

To meet the challenges of integrating quality into an organization's everyday compliance efforts, organizations must first educate top executives within the organization on the importance of integrating quality and compliance.

Organizations should emphasize that current quality reporting programs and financial disincentives for poor quality of care are a few of the first steps implemented by the government in a progression to VBP. The latter VBP initiative was authorized by the DRA, which required the Secretary of Health and Human Services to designate hospital-acquired conditions that are:

- either high cost or high volume or both;
- result in the assignment of a patient to a Medicare diagnosis-related group (DRG) that has a higher payment when present as a secondary diagnosis; and
- could reasonably have been prevented through the application of evidence-based guidelines.

For discharges occurring after October 1, 2008, hospitals will not receive additional payment for patients when one of the selected conditions was not present on admission (i.e., the case will be paid as though the secondary diagnosis was not present and the hospital cannot bill the beneficiary for any charges associated with the hospital-acquired condition). CMS has identified ten hospital-acquired conditions for potential reduced payment: catheter-associated urinary tract infections, vascular catheter-associated blood stream infection, surgical site infection, object left in surgery, air embolism, blood incompatibility, pressure ulcers, falls, venous thromboembolism, and poor glycemic control.

Leadership within the organization must understand the potential impact that quality will have on:

- the organization's financial performance, as payment becomes increasingly tied to quality of care;
- the organization's standing in the community, as the public becomes increasingly aware of quality outcomes; and
- the risk of government enforcement based on quality failures, because most organizations do not scrutinize quality of care for

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compliance implications as they scrutinize other compliance concerns (e.g., billing, claims submission, physician financial relationships).

As organizations grapple with integrating quality into compliance, they should focus on revamping each of the several elements of an effective compliance program to incorporate quality. An effective compliance program begins with the commitment of the governing board and requires the participation of staff at all levels, including officers, managers, supervisors, employees, physicians, independent contractors, and other agents.

The elements of an effective compliance program are:

- Written compliance policies and procedures that identify specific compliance risks to the organization;
- Defined standards of conduct that demonstrate the organization's commitment to compliance;
- Designation of a senior level compliance officer and compliance committee with authority to oversee the development and implementation of the compliance program;
- Effective training and education programs;
- Development of effective lines of communication;
- Enforcement of standards of conduct through well-publicized disciplinary guidelines;
- An auditing and monitoring program; and
- Effective responses to detected offenses including the development of corrective action initiatives.[4]

As shown in the OIG report on nursing homes, making quality part of the organization's compliance program will improve quality-of-care structures and processes and minimize exposure to FCA liability as well as other legal risks.

Written policies and procedures

Written policies and procedures are the cornerstone to an effective compliance program. They are designed to create a culture that promotes prevention, detection, and resolution of conduct that does not conform to federal and state law, government and private payer requirements, or the organization's policies. The policies and procedures should be developed under the direction and supervision of the chief compliance officer (CCO) and the organization's Compliance committee and should identify the organization's specific risk areas.

To ensure compliance at all levels of the organization, all individuals who are affected by the policies, including independent contractors and agents, should receive a copy of the policies and procedures and should be knowledgeable on the relevant elements of the compliance program. A first step to integrating quality into compliance involves a review of the organization's compliance policies, and the development of new ones, that give guidance on how governmental mandates regarding quality will be met.

Standards of conduct

Standards of conduct are a key component of an organization's compliance program, because they demonstrate an organization's commitment to compliance and the prevention of fraud and abuse. Not only do the standards of conduct articulate the organization's mission, goals, and ethical requirements, but they also establish expectations for the governing board, officers, managers, employees, and, where appropriate, independent contractors and other agents. Organizational standards of conduct should be reviewed to make sure that quality, patient safety, and the delivery of medically necessary care are key requirements to be adhered to at all levels of the organization. These standards of conduct should be distributed and made available to the employees in a language the employees understand and at an appropriate reading level. Additionally, a specific agreement to adhere to the standards of conduct should be made a part of orientation for staff and physicians, and specific training about the standards should be part of the compliance education program. Finally, the standards should be regularly reviewed and updated to comply with the latest changes to applicable federal and state standards and payer requirements.

Risk assessments

Identification of an organization's risk areas is another crucial element of the compliance program. Accordingly, the implementation of the compliance program should be guided by a risk assessment of the regulatory exposure for each function or department of the organization. A quality-of-care risk assessment should be undertaken to assess the specific risks presented by, among other risk areas:

- the Medicare Conditions of Participation requirements;
- important billing concerns, such as coding of present-on-admission and hospital-acquired conditions indicators;
- the processes in place to ensure the provision of only medically necessary care; and
- quality data reporting.

Based on the results of a quality risk assessment, the organization can target the development of policies, procedures, training programs, and auditing/monitoring programs to specifically address the organization's identified risk areas.

Chief compliance officer and Compliance Committee

Another key component to an effective quality-of-care compliance program is the CCO and a Compliance Committee. To ensure appropriate allocation of resources to

investigate and resolve compliance issues, the CCO should be a high-level official who has direct access to the organization's governing board and chief executive officer. Working in conjunction with the Compliance Committee, the CCO is responsible for developing a compliance program that addresses the organization's needs and complies with federal and state laws and regulations, and the policies and procedures of government and private payers. Now that quality is an important compliance concern, the CCO must interface directly with the senior management of the organization's Quality, Risk, Utilization Review and Billing departments, and with the medical staff office, to ensure that the compliance implications associated with quality failures are appropriately addressed.

Working in conjunction with the CCO, the compliance committee is integral to the implementation and oversight of the compliance program. Because quality is now a central focus of the Compliance Committee's responsibilities, organizations should consider the composition of the committee to ensure that Quality, Risk, Finance, Utilization Review and the medical staff office are represented, so that important quality related compliance issues can be incorporated into the program.

Education and training programs

Education and training of all personnel affected by the integration of quality of care into the compliance program is essential to the success of the compliance program. The CCO should begin educating and training the board of directors and top executives within the organization on the importance of quality, as discussed above, so that quality becomes a top priority equal to the organization's financial performance.

In September 2007, OIG and the American Health Lawyers Association released their third joint publication to advise boards of directors that quality of care is among their top fiduciary obligations.[5] All health care organizations should ensure that their boards have reviewed this publication and understand the answers to the ten questions posed in the guidance as to how the organization is dealing with quality and its compliance implications. In addition, education and training regarding quality of care and its compliance implications should be provided to all levels of individuals within the organization, including corporate officers, managers, employees, independent contractors, physicians, and other health care professionals. Training and education on quality of care as a compliance issue should be provided in orientation and in the organization's annual education and training sessions. In an ongoing effort to improve quality of care, the CCO should offer targeted training, based on risk areas identified by periodic risk assessments and audits, and encourage coordination among top executives and other personnel to reduce quality risks. The CCO, with the assistance of the Compliance Committee, should regularly update the content of the education and training programs that are offered on a regular basis, to ensure all personnel have been trained and are up-to-date on the top quality issues that affect the organization.

Effective lines of communication

An essential component of maintaining an effective quality-of-care compliance program is the ability to identify and respond to quality issues. An effective tool to be used for identifying quality issues as they arise is the established lines of communication among the CCO, Compliance Committee, and personnel of the organization. The open line of communication, often used in compliance programs, is facilitated through an anonymous hotline.

Establishing open lines of communication among the CCO, Compliance Committee, and other departments to exchange quality-of-care information should not been done without careful consideration of the applicable privileges that may apply to quality information. In establishing these open lines of communication, the CCO should work closely with legal counsel to develop a process to exchange compliance information regarding quality-of-care issues to maximize state peer review protections and privileges.

Auditing and monitoring

To ensure the integrity and effectiveness of the compliance program, an essential element is the ongoing evaluation and monitoring of compliance risk areas. This is generally accomplished through the development and implementation of detailed annual audit plans to ferret out and correct practices that may lead to compliance violations or failures. As these audit plans are developed, the Compliance Committee and CCO should consider the results of quality risk assessments or information reported through its monitoring programs, including quality issues in the areas audited on an annual basis. Quality issues subject to audit may include the medical necessity of certain services or procedures, hospital-acquired conditions reporting, and quality reporting data and processes, to name a few. The precise issues chosen by the organization's CCO and Compliance Committee should be based on those areas of risk uncovered through periodic risk assessments and those reported through its monitoring programs.

Response to detected offenses

When made aware of any potential quality-of-care issues, whether through a hotline, patient complaints, or risk assessments, the CCO should initiate prompt steps to investigate the possible compliance issues arising from the event. For example, if the

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CCO learns about instances of medically unnecessary care, a response team should be formed to assist the CCO to investigate the issue, determine the corrective steps to remediate the quality-of-care issues, and consider whether reporting or repayment is indicated. These internal investigations should be done under the direction of counsel to obtain the protection of the attorney/client privilege, and may require the assistance of auditors and experts to assess the risk and develop a corrective action plan. In some cases, it may be appropriate for the CCO to work hand-in-hand with the medical staff office.

Breakdown of silos

One of the primary obstacles to implementing an effective quality-of-care compliance program is the current departmental structure that exists in many large health care organizations. Traditionally, quality has been addressed piecemeal through an organization's quality assurance, risk management, utilization review, and in the case of hospitals, peer review programs. These programs generally are designed to evaluate isolated, past incidents of non-compliance and do not focus proactively on overall quality of care or identify, in advance, high-risk practice patterns.

Additionally, these quality-of-care programs generally are separate and distinct from the organization's compliance program, and historically, quality has not received the same level of attention as the organization's other compliance concerns, such as billing and claims submission and physician financial relationships. In addition, while the organization's quality, risk management, and peer review programs all deal with quality-of-care issues on some level, the siloed structure does not facilitate the exchange of information between individuals involved in these programs. As a result, information critical to identifying and addressing compliance risks that arise from substandard quality of care often is not known by those individuals in the organization who view the issues through a compliance lens. This leaves the organization vulnerable to potential fraud claims and other liabilities. Accordingly, integrating the organizational structure of historically disparate departments is critical to an effective quality of care compliance program.

The OIG's conclusion that quality-of-care CIAs caused these 15 nursing home corporations to enhance quality-of-care structures and processes in their systems is important information for all

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hospitals, nursing homes, and other providers who are subject to quality reporting by CMS. This study supports the fact that integrating quality into compliance is not simply a good idea, but it has been found to actually improve overall quality processes and structures—a positive step that is likely to improve overall performance on quality targets. All health care providers, not just nursing home corporations, should take steps now to integrate quality and compliance as a way to prepare for the changes to come when payment itself will depend on its performance in meeting quality targets. ■

1 OIG Report: The Nursing Home Corporations Under Quality of Care Corporate Integrity Agreements. Available at http://www.oig.hhs.gov/oei/reports/oei-06-06-00570.pdf.
2 421 F.3d 817 (9th Cir. 2005)
3 31 U.S.C. §§3729-3733
4 OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987 (Feb. 23, 1998)
5 Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors. Available at http://www.oig.hhs.gov/fraud/docs/complianceguidance/CorporateResponsibilityFinal%209-4-07.pdf.

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