CCH Health Care Compliance LETTER

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Evaluating compliance programs: Beyond self-assessment

by Susan L. Smith, J.D., M.A., Contributing Editor

Compliance officers must plan for and conduct an audit of their organizations' compliance program at least annually, according to Glen C. Mueller, Vice President and Chief Audit & Compliance Officer at Scripps Health in San Diego, California. Speaking at a break out session at the Health Care Compliance Association's 2007 Compliance Institute held in Chicago, Illinois, on April 22-25, Mueller advised that this annual audit is necessary to ensure program effectiveness.

An audit is a periodic assessment of a compliance program and requires evaluating the quality of compliance program management. Internal audit committees are required to conduct an audit every five years and report their findings to the board, Mueller noted. He cautioned compliance officers, however, to get out ahead of the governing board and audit committee by reviewing implementation and execution of the compliance program. "Don't wait five years to see if the program is effective," he stressed.

Core documents. According to Mueller, the starting point in determining the effectiveness of a compliance program is to examine three core documents: the risk assessment tool, the auditing and monitoring plan, and the corporate compliance plan. Any review should start with these three documents.

To measure effectiveness, certain questions should be answered:

- Looking a year in arrears, have the auditing, monitoring, and training plans been executed?
- How does the organization use data to drive change as necessary in the organization?
- How does the organization tackle the root cause of the problem?
- Can the organization show by its data that it has effectively controlled issues that arise?

Review methods. Mueller outlined four methods for reviewing an organization's compliance program:

(1) Self-assessment by the compliance department.

(2) Internal audit, including self-assessment in conjunction with a review by the organization's audit department. In considering this method of review, Mueller said it is important to know whether the audit committee understands the organization's compliance program. Internal audits explore how well a program is managed and whether internal controls are effective. If the audit committee does not understand the compliance program, important elements may not be reviewed appropriately.

Wolters Kluwer Law & Business

(3) Third-party independent validation conducted by a consultant or outside compliance officer.
(4) A complete third-party review by a consultant or outside peers, such as other compliance officers. Even with an independent review, a self-assessment should be done.

A conference participant cautioned that when working with third party reviewers, organizations should be aware of hidden agendas that might be part of any recommendation given by outside consultants. For reviews conducted by an outside compliance officer, another participant recommended that the outside compliance officer be associated or have experience with a similarly situated facility. For example, the review of a rural hospital should not be conducted by a compliance officer from a large metropolitan hospital whose issues and resources may be very different.

Independent review v. self-assessment. An independent review provides senior management some level of comfort, Mueller said. Although oversight of the compliance program is part of the due diligence for which the government is looking, there are various levels of oversight, from self assessment, which would be minimal, to internal audit, which would be more extensive. An outside reviewer can help understand organizational compliance in relation to resources, including the quality of the risk assessment tool and the auditing and monitoring plan. In addition, a peer review by an independent reviewer provides an opportunity to borrow processes or procedures that have proven effective for other compliance plans.

Expectations and gap analysis. Compliance officers should confirm that the expectations of management and the board match the expectations of the consultant or peer reviewer. Confirming the board's risk acceptance tolerance provides an opportunity to look at risks that the organization may not be addressing.

A gap analysis looks at where the organization is and what it needs to do. Specifically, the analysis looks at risks, policies, controls, staffing needs, communications, and compliance-enhancing resources. It identifies what ought to happen that hasn't happened yet.

Mueller recommends scheduled reports to the board semiannually with quarterly reports to senior management. Reports should include dates of prior recommendations and dates for follow-up. Reporting to the board can provide a powerful incentive for compliance within the organization, especially if the board takes action when the compliance officer lacks authority to do so.

CCH Chicago Bureau, May 2, 2007.

Medicare

CMS proposes quality of care incentives for home health agencies

by Jenny Burke, J.D., Contributing Editor

Changes to the home health prospective payment system (HH PPS) are designed to ensure more appropriate payment for services provided by Medicare home health agencies (HHAs), while establishing incentives for more efficient care for Medicare beneficiaries. According to CMS Acting Administrator Leslie V. Norwalk, the HH PPS proposed rule, issued by CMS on April 27, 2007, "furthers Medicare's commitment toward making accurate payments in all of its payment systems [and] seeks to improve the appropriateness and performance of care for Medicare beneficiaries."

To avoid any additional burden and related costs associated with using a new reporting mechanism, CMS proposes to evaluate home health care quality by continuing to rely on the submission of Outcome and Assessment Information Set data collected by HHAs. The proposed rule includes a provision that would continue to adjust the payment for reporting quality data. HHAs that submit the required quality data would receive payments based on the proposed full home health market basket update of 2.9 percent for calendar year (CY) 2008. If a HHA does not submit quality data, the home health market basket percentage increase would be reduced by 2 percentage points to 0.9 percent.

CMS publicly reports the nationally accepted and approved quality measures on the Medicare Home Health Compare website. For CY 2008, CMS

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is proposing to add two National Quality Forum-endorsed measures to the 10 that are currently reported: emergent care for wound infections - deteriorating wound status; and improvement in status of surgical wound. According to Norwalk, "The continued improvement in the quality of and access to home health services will be enhanced through this additional public reporting of quality information."

CMS Press Release, April 27, 2007.

Hospitals required to provide basic emergency care

by Valerie L. Witmer, J.D., Contributing Editor

Medicare's long-standing requirement that hospitals be able to address individuals' emergency care needs 24 hours a day, 7 days a week remains a key part of CMS' overall strategy to ensure safe, quality care for all Medicare beneficiaries. In a Survey and Certification letter issued on April 26, 2007, CMS clarified the responsibility of hospitals to provide basic emergency services if they participate in the Medicare program.

Any hospital participating in Medicare, regardless of the type of hospital and regardless of whether the hospital has an emergency department, must have the capability to provide basic emergency care interventions. According to the guidance document, this means hospitals must satisfy three key requirements: (1) appraisal of individuals with emergency medical conditions; (2) initial treatment; and (3) referral when appropriate. These requirements apply to nearly all hospitals, including specialty hospitals and others without emergency departments. CMS emphasized that hospitals without emergency departments, nonetheless, must have appropriate policies and procedures in place for addressing individuals' emergency care needs. The requirements do not apply to critical access hospitals, which are governed by separate regulations.

Appraisal. Hospitals must have medical staff policies and procedures for evaluating patients with emergency medical conditions. The policies and procedures must take into account all relevant Conditions of Participation (CoPs) and ensure that (1) a registered nurse (RN) is immediately available to provide bedside care to any patient; and (2) among the RNs who are immediately available at all times, there is at least one RN who is qualified to assess an individual's need for emergency care. The appraisal policies and procedures also should provide that the on-site or on-call physician would directly provide appraisals of emergencies or provide medical direction of on-site staff conducting appraisals.

Initial treatment. Hospitals must have medical staff policies and procedures for providing the initial treatment needed by individuals with emergency medical conditions. Among the RNs who are immediately available at all times, there must be at least one RN who is qualified to provide that initial treatment. The on-site or on-call physician could provide initial treatment directly or provide medical direction and oversight to other staff.

Referral. Hospitals must have medical staff policies and procedures to address situations in which a person's emergency needs may exceed the hospitals' capabilities. The policies and procedures should enable hospital staff to: (1) recognize when a person requires a referral or transfer; and (2) assure appropriate handling of the transfer, including arrangement for appropriate transport of the patient and transfer to facilities with the appropriate capabilities to handle the patient's condition. The transferring hospital also must send necessary medical information along with the patient to facilitate efficient treatment by the receiving hospital.

The guidance emphasized that hospitals may not rely on 9-1-1 services as a substitute for the emergency response capabilities the hospitals are required to maintain. This means, among other things, that a hospital may not rely on 9-1-1 to provide appraisal and initial treatment of medical emergencies that occur at the hospital. Any such hospital procedure or practice would be considered condition-level noncompliance with the CoPs.

Transparency and public disclosure. In another recent development, CMS issued a proposed rule that would increase transparency and public disclosure with respect to emergency services.

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On The Front Lines

Risk managing the CMS rule on restraints & seclusion

by Fay Rozovsky, J.D., M.P.H., Contributing Editor

This is Part I of a two-part article that highlights risk management concerns implicated by the new CMS rule on the use of restraints and seclusion and provides strategies for shaping hospital policy and procedure to promote patient safety and avoid prohibited practices. Part I discusses the rationale for the regulatory change, the meaning of restraint and seclusion within the regulatory scheme, and proper use of restraints and seclusion.

On January 8, 2007, CMS implemented the final rule on the use of restraints and seclusion in hospitals.[1] The rule applies to hospitals receiving Medicare and Medicaid funding, and replaces the interim regulation issued in July 1999. At the same time, CMS finalized without any changes all the existing provisions for hospitals regarding patient notification of rights, exercise of rights, privacy, and safety, as well as confidentiality of medical records.

Streamlined in content, the final rule sets a "minimal threshold" for hospitals. It accounts for the possibility that some state laws will be more stringent than the federal requirements and, in those instances, requires that hospitals comply with the higher standard of care.

From a risk management perspective, the final rule highlights seven major areas of change. These areas are described here along with risk management strategies for transforming the regulation into daily practice in the hospital setting.

Theme for change

As is often the case, the preamble to the final rule provides useful insights into the rationale for regulatory change. CMS recognizes the legitimate use of restraints to prevent injury to medical or surgical patients and to manage violent or self-destructive behavior that jeopardizes the *immediate* physical safety of staff, patients, or others. The overarching theme of the preamble is patient safety, freedom from abuse, and inappropriate use of restraints and seclusion.

The preamble in context

The preamble is not considered the text of the regulation. As such, it is not enforceable like the actual provisions of the final rule. Rather, it offers useful insights into how CMS is likely to enforce the regulation. Along with the interpretive guidelines that will be published later for this final rule, the preamble can be used as a guide or roadmap for necessary changes in hospital policies, procedures, and practice routines.

Meaning of restraint and seclusion

To remove any ambiguity about the meaning of restraint and seclusion, CMS provided definitions in the final rule. A "restraint" is defined as:

> (A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or
>
> (B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.[2]

CMS also identified what *does not* constitute a restraint:

> [D]evices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).[3]

The final rule defines "seclusion" as:

> [T]he involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.[4]

To be certain that hospitals understand the application of the definitions, the preamble offers some direction. For example, CMS offered this explanation with regard to bedrails as a type of restraint:

The final regulation states that devices that protect the patient from falling out of bed are not restraints. However, when the clinician raises all four side rails to restrain a patient (defined in this regulation as immobilizing or reducing the ability of a patient to move his or her arms, legs, body, or head freely) to ensure the immediate physical safety of the patient then the rule applies. Raising fewer than four side rails, would not necessarily immobilize or reduce the ability of a patient to move as defined in this regulation.[5]

Proper use of restraints and seclusion

The final rule describes when and how to use restraints and seclusion appropriately. Restraints or seclusion should be used *only when it has been determined that less restrictive measures are ineffective* to protect the patient, a staff member, or others from harm. It requires a written change to the patient's care plan. Moreover, the method chosen must be consistent with hospital policy and state law.[6]

"The overarching theme of the preamble is patient safety, freedom from abuse, and inappropriate use of restraints and seclusion."

Order for restraints or seclusion

Restraints and seclusion must be ordered by a physician or licensed independent practitioner who is responsible for the patient's care and authorized to order the use of restraints or seclusion under hospital policy and state law. If the attending physician was not the care provider who issued the order, he or she must be consulted as soon as possible.[7]

Face-to-face evaluation

When a restraint or seclusion is implemented to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or other individuals, the patient must be seen face-to-face within one hour of the intervention. This face-to-face encounter includes an evaluation that must be carried out by a physician or licensed independent practitioner (LIP). The evaluation also may be conducted by a registered nurse (RN) or physician assistant (PA) who has received the type of training described in the regulation. The person carrying out the evaluation must assess four factors:

(A) the patient's immediate situation;
(B) the patient's reaction to the intervention;
(C) the patient's medical and behavioral condition; and
(D) the need to continue or terminate the restraint or seclusion.[8]

Need to consult the attending physician

When the evaluation is done by an RN or PA trained for this purpose, he or she must consult the attending physician as soon as possible after completing the assessment. CMS made clear that a state might impose more stringent requirements through legislation or regulation. Thus, a state might allow only a physician to carry out the evaluation.[9]

Licensed independent practitioner

A key issue for many risk managers is determining who fits the definition of a LIP. A review of the preamble suggests some reservation on the part of CMS with respect to delegation to LIPs:

> For the purpose of this rule, a LIP is any individual permitted by State law and hospital policy to order restraints and seclusion for patients independently, within the scope of the individual's license and consistent with the individually granted clinical privileges. This provision is not to be construed to limit the authority of a physician to delegate tasks to other qualified healthcare personnel, that is, physician assistants and advanced practice nurses, to the extent recognized under State law or a State's regulatory mechanism or hospital policy.[10]

The consultation with the attending physician was a provision found in the interim rule. Along with the issue of delegation, CMS wanted to be certain that following the initiation of restraint or seclusion, the assessment was carried out by a qualified person. Thus, in the preamble CMS stated:

> The continued physician accountability for actions taken under his or her licenses provides a direct incentive for taking the decision to delegate very seriously....[C]linical psychologists or other practitioners who may be authorized by the State to order restraint or seclusion may lack the technical medical skills and training to conduct a comprehensive physical assessment. Therefore, the practitioner who conducts the 1-hour face-to-face evaluation must be able to complete, under their scope of practice, both a physical and psychological assessment of the patient.[11]

Combined use of restraints and seclusion

CMS made clear in the final rule that restraints and seclusion could be used simultaneously. In such cases, the patient must be monitored face-to-face by a staff member who is properly trained and assigned to complete this responsibility

or training personnel using video and audio monitoring equipment. Further, the monitoring must be done in close proximity to the patient so staff can intervene rapidly if necessary.[12]

Time limits on restraints and seclusion

The regulation includes time limits for the use of restraints and seclusion. Each order for restraints or seclusion may be renewed in accordance with the following limits for up to a total of 24 hours:

- 4 hours for adults 18 years of age or older;
- 2 hours for children and adolescents 9 to 17 years of age; and
- 1 hour for children under 9 years of age.

After the 24-hour time period, the physician or LIP responsible for the patient's care authorized to order restraints and seclusion must see and assess the patient before issuing a new written order for the same type of intervention. The basis for issuing the new order remains the same: managing violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, staff, and other individuals.[14]

CMS made it clear that, notwithstanding the time period set forth in the order, the restraints or seclusion should be terminated as soon as possible.[15]

Conclusion

Part I of this article discussed the rationale for the changes implemented by the final rule, the meaning of restraint and seclusion within the regulatory scheme, and proper use of restraints and seclusion. Part II discusses requirements for training in the use of restraints and seclusion, reporting deaths associated with the use of restraints and seclusion, and training and clinical documentation. It also provides strategies for shaping hospital policy and procedure to promote patient safety and avoid prohibited practices.

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1 *Final rule*, 71 FR 71377, 71377-428, Dec.8, 2006.
2 *Id.* at 71377-427.
3 *Id.*
4 *Id.*
5 *Id.*
6 *Id.*
7 *Id.*
8 *Id.*
9 *Id.*
10 *Id.* at 71394.
11 *Id.*
12 *Id.* at 71427.
13 *Id.*
14 *Id.*
15 *Id.*

OIG to focus on illegal physician arrangements

by Stacey Fahrner, J.D., M.P.H., Contributing Editor

Physicians can no longer assume they are off the government's radar in kickback cases, according to experts who spoke during the Health Care Compliance Association's 2007 Compliance Institute in Chicago, Illinois, on Tuesday April 24, 2007. According to Spencer Turnbill, J.D., Office of Counsel to the Inspector General (OCIG), "the government wants to increase the deterrent effect to physicians."

Although anti-kickback enforcement in the past was driven primarily by "*qui tam*" suits, which targeted entities because of the potential for large pay-outs, under the Civil Money Penalties law (CMP) the government now has greater flexibility to pursue recipients of illegal kickbacks.

The CMP is a powerful tool for the Office of Inspector General (OIG) because it allows for the administrative enforcement of the anti-kickback statute, which would otherwise be enforced criminally through the Department of Justice. The CMP requires a lower standard of proof to find wrong doing: "preponderance of the evidence" as opposed to the "beyond a reasonable doubt" standard under the criminal justice system. In addition, administrative actions have more liberal rules of evidence, and sanctions can be closely tailored to the wrongful act. Administrative actions also provide an efficient mechanism through which the OIG can pursue smaller scale cases.

Physician-hospital relationships. According to Turnbill, because of the flexibility under the CMP, there will be an increase in the number of cases targeting physician-hospital relationships. Kevin McAnaney, of the Law Offices of Kevin McAnaney, noted that there are four problematic areas on which the government may focus:

- Space and equipment leases. Space and equipment leases for less than fair market value are an ongoing concern of the OIG. McAnaney cautioned that all transactions between hospitals and physicians must be arm's length, even when they are at fair market value. Furthermore, space leased to physicians should not exceed the needs of the practice.
- Physician compensation arrangements. According to the presenters, the government continues to find compensa-

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Medicare (cont.)

The fiscal year 2008 acute care hospital inpatient prospective payment system proposed rule would require a hospital to notify all patients in writing if a physician is not present in the hospital 24 hours a day, 7 days a week. In such cases, the hospital would be required to disclose how it would meet patients' emergency medical needs while no physician is on-site.

According to Leslie V. Norwalk, Esq., Acting Administrator of CMS, this guidance "is part of an overall strategy to ensure quality care by assuring the rapid response to emergencies for all people with Medicare."

CMS Press Release, April 26, 2007; Survey & Certification Letter, S&C-07-19, April 26, 2007, Health Care Compliance Reporter ¶350,035.

Anti-Kickback (cont.)

tion arrangements between hospitals and physicians when no real services are rendered. Compensation arrangements must be at fair market value for actual services rendered. Physicians should be cautioned that all services must be accurately documented.

- "Under arrangements." The "under arrangements" model allows the hospital to bill Medicare for services performed under arrangement with another entity. The hospital then pays the entity for the value of the procedure. While these arrangements are legal, they can be a disguise for prohibited referrals. Payments to the physician or group under arrangement with the hospital should be at fair market value. The method of selecting physicians for the arrangement should be evaluated to ensure the arrangement does not run afoul of the Stark or anti-kickback laws.
- Joint ventures. According to both Turnbill and McAnaney, physician-hospital joint ventures will continue to be an area of concern.

Physician relationships with device manufacturers. Because of the high risk for kickbacks, physician relationships with device manufacturers are of increasing interest to the government. According to Turnbill, device cases are relatively simple to prosecute. They generally involve straightforward kickbacks, as opposed to complicated fraud schemes, and are easy for a jury to understand. Red flags include:

- Consultant payments to physicians for little or no work, and the use of physicians for marketing purposes. If physicians are paid for consulting services, there should be a legitimate need for those services, and the physicians should be paid the fair market value of the services.
- Research grants to physicians for little work or unnecessary work. Grants should be provided at the fair market value for legitimate services. Such arrangements should fit into the personal services safe harbor when possible.
- Physician investment in the device company. Investment can be used as a mechanism to solicit kickbacks from hospitals and raises quality of care issues.

The presenters cautioned that all physician business arrangements should be evaluated to ensure that they are arm's length transactions for fair market value. These arrangements cannot be a mechanism for generating referrals.

CCH Chicago Bureau, April 24, 2007.

Information Technology

E-prescribing standards will cut errors, costs

by Valerie L. Witmer, J.D., Contributing Editor

The results of an electronic prescribing pilot project support the adoption of new electronic prescribing standards, according to HHS Secretary Michael Leavitt. These standards, required by the Medicare Modernization Act of 2003 (PubLNo 108-173), would help reduce medical errors and health care costs.

The pilot project, conducted through an interagency agreement between CMS and the Agency for Healthcare Research and Quality, selected five pilot sites operating in eight states to test initial e-prescribing standards to determine if they were ready for widespread adoption. The findings showed that three initial standards currently are capable of supporting e-prescribing transactions that provide physicians with patients' formulary and benefit information, medication history, and the fill status of their medications. The project also found that, with some adjustments, e-prescribing can work successfully in long term care settings.

Some of the initial e-prescribing standards tested by the pilot project were found to have potential but still need further development if they are to be adopted as e-prescribing standards. These include standards used to convey structured patient instructions, a terminology to describe clinical drugs, and messages that convey prior authorization information.

"Electronic prescribing improves efficiencies while helping to eliminate potentially harmful drug interactions and other medication problems....Additionally, such health information technologies promote affordability by allowing physicians to know which medications are covered by their patients' Part D plans," Leavitt said. "The findings in this report, along with previously adopted foundation standards, demonstrate that HHS is effectively advancing electronic prescribing which will continue to help Medicare beneficiaries receive higher quality care."

HHS Press Release, April 17, 2007.

In the News

Florida legislature passes false claims bill

The Florida House and Senate have passed a bill that, when signed into law, will mirror the federal False Claims Act (FCA). The FCA allows the Attorney General's Medicaid Fraud Control Unit (MFCU) to recover triple damages in civil lawsuits against those who commit Medicaid fraud. This legislation will increase the recovery for Florida by 10 percent on all civil actions. In 2005, Florida's MFCU secured over $76 million in settlements, nearly all of which was recovered through the use of the FCA. Florida Attorney General Bill McCollum stated, "I commend the Legislature for passing this important legislation which will assist our state [to] combat Medicaid fraud and punish those who selfishly cheat the system." The bill now goes to the Governor to be signed into law.

Florida Attorney General Press Release, May 2, 2007.

AG settles first security breach notification law case

New York's Attorney General has announced the first settlement under the state's Information Security Breach and Notification Law. A Chicago-based claims management company failed to notify the owner of computerized data and approximately 540,000 New York consumers that their personal information was at risk for seven weeks after an employee noticed that a computer housing the information – which included the names, addresses, and social security numbers of recipients of workers' compensation benefits – was missing. Under New York's notification law, any business that maintains private information that it does not own must notify the owner of the data of any security breach "immediately following discovery" of the breach and must notify all affected consumers in the "most expedient time possible." The company has agreed to implement precautionary procedures and comply with New York's notification law in the event of a security breach.

New York Attorney General Press Release, April 26, 2007.

CMS launches health IT learning system

CMS has announced the national launch of Doctor's Office Quality Information Technology University (DOQ-IT U) to support health information technology (HIT) in physicians' offices. The interactive, Web-based system will provide lessons in assessment, planning, and implementation methodologies that will be disease and population specific, incorporating clinical decision support and evidence-based medicine guidelines. The first learning sessions focus on physician office workflow redesign, culture change, and communication necessary for successful electronic health record adoption, implementation of care management, and incorporation of a strong patient self-management component to clinical care. Disease-specific sessions will include a patient self-management component, which is critical to successfully managing patients with chronic disease. According to CMS Acting Administrator Leslie V. Norwalk, DOQ-IT U is intended to "provide physicians with easy access to the resources they need to help ensure that patients receive the highest quality of care at all times."

CMS Press Release, April 11, 2007.