

Compliance with Medicare's Conditions of Participation for hospitals

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Hospitals, generally, must be Medicare certified in order to receive reimbursement for services provided to Medicare beneficiaries. This requires hospitals to be in continual compliance with federal regulations known as the Conditions of Participation (CoPs). Compliance with CoPs has always been important for Medicare-certified hospitals. The Centers for Medicare and Medicaid Services (CMS) can terminate non-compliant hospitals' participation in the Medicare program. Although an action by CMS to terminate a hospital's Medicare participation is an alarming experience, actual termination is very rare. CMS is required to provide hospitals with notice of the planned decertification and give them the opportunity to submit plans of correction to demonstrate continuing compliance. Most hospitals that receive termination action notices quickly come into compliance to avoid termination.

Recently, however, the federal government adopted a new method to sanction hospitals that do not comply with CoPs. The government now is using the False Claims Act (FCA)¹ and alleging that submit-

ting claims for services rendered without complying with CoPs is tantamount to fraud. Although compliance with the CoPs previously was largely an "operations" concern, now the hospital's compliance program must be attentive to the potential consequences of noncompliance with CoPs. The consequences may affect the hospital's ability to seek payment and have attendant enforcement vulnerabilities.

Condition of participation: Restraint and seclusion

On January 8, 2007, significant revisions to the restraint and seclusion CoP became effective.² These revisions included redefining "restraint," changing the requirements for implementation and monitoring of patients in restraints or seclusion, adding detailed staff training requirements, and expanding the hospital reporting requirements. Because of the scope of changes, compliance with this new CoP may become a significant focus in the federal government's FCA actions against hospitals.

Restraint and Seclusion Defined. In the new standard, "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.

According to the regulation, restraints do not include: devices, such as orthopedically prescribed devices, surgical dressings or bandages, pro-

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JANICE ANDERSON



rective 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).

CMS also defines seclusion in the regulation as: the 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.³

Use of restraint and seclusion

The revised CoP restricts the use of restraint or seclusion to those situations where less restrictive interventions are determined to be ineffective to protect the patient, a staff member, or others from harm, and a hospital may only use the least restrictive type or technique that will be effective to provide protection. Restraint or seclusion orders may never be ordered “as needed,” or “PRN” [*Pro Re Nata* (Latin: for the existing occasion; as needed)] and may be used only in accordance with a written modification to the patient’s plan of care. The use must be ordered by a physician or other licensed independent practitioner (LIP) who is responsible for the care of the patient and authorized to order restraint or seclusion by hospital policy in accordance with state law.⁴ If the attending physician did not order the restraint or seclusion, he or she must be consulted as soon as possible.

The revised CoP emphasizes that restraints must be implemented in accordance with safe and appropriate restraint and seclusion techniques, as determined by hospital policy and in accordance with state law. Unless state law is more restrictive, an order for restraint of a non-violent or non-self-destructive patient may be renewed in compliance with hospital policy. If, however, the restraint or seclusion of a

patient is ordered for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the order must be time-limited: the restraint or seclusion order may not last more than four hours for adults 18 years or older, two hours for children 9-17 years old, or one hour for children under 9 years old. These orders can be renewed for a total for 24 hours; after 24 hours, a physician or other LIP responsible for care of the patient must see and assess the patient before writing a new order.

While a patient is in restraint or seclusion, his or her condition must be monitored by a physician or LIP, or by staff who have completed training detailed in the regulation. If the restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within one hour after initiation of the intervention by a physician, LIP, or a registered nurse (RN) or physicians assistant (PA) who has received training required by the regulation. That face-to-face encounter must be used to evaluate the patient’s immediate situation, the patient’s reaction to the intervention, the patient’s medical and behavioral condition, and the need to continue or terminate the restraint or seclusion. If the face-to-face evaluation is conducted by a RN or PA, he or she must consult as soon as possible with the attending physician or LIP responsible for the patient’s care.

If the patient is in restraints and seclusion, all of the requirements discussed above apply. Further, the patient must be continually monitored by either an assigned, trained staff member using both video and audio equipment or by trained staff in close proximity to the patient.

Medical Record Requirements. The CoP also details what information must be in the medical record:

- The one-hour face-to-face medical and behavioral evaluation (if the restraint or seclusion is used to manage violent or self-destructive behavior)
- A description of the patient’s behavior and the intervention used
- Alternatives or other less restrictive interventions attempted (if applicable)
- The patient’s condition or symptoms that warranted the restraint or seclusion

Continued on page 11

- The patient's response to the intervention, including the rationale for the continued use of the intervention

Although not required by the regulation, good documentation should also include mandatory staff consults with the physician and assessments by the care team (including the physician) during the time the patient is restrained.

Staff training requirements

The revised regulation adds extensive staff training requirements, mandating hospitals to train staff before those staff members can perform any of these actions:

- application of restraints
- implementation of seclusion
- monitoring, assessing, and providing care for patients in restraints or seclusion.

This training must be part of orientation and must occur subsequently on a periodic basis consistent with hospital policy. Hospital policy also must specify training requirements for physicians and other LIPs, who, at a minimum, must have a working knowledge of the hospital's restraint policy.

Reporting requirements

CMS has extended the reporting requirements. Under the prior rule, hospitals had to report to CMS any death that occurred while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion. The revised CoP requires hospitals to report to CMS deaths that occur (a) while a patient is restrained or in seclusion, (b) within 24 hours after the patient has been removed from restraints or seclusion, or (c) within one week after restraint or seclusion where it is reasonable to assume that the use of restraints or seclusion contributed to the patient's death. CMS requires hospitals to make the report by telephone no later than the close of business the next business day following knowledge of the patient's death, and hospitals must record in the patient's medical record that they notified CMS.

FCA liability for failing to meet the revised CoP

The FCA risks for failing to comply with a CoP remain somewhat uncertain at this time. Although recent cases highlight the government's intent since the mid-1990s to use the FCA to prosecute hospitals that fail to follow CoPs, the government has pursued FCA claims against health care facilities on an "implied certification" theory of liability with varying success. This theory is based on the concept that when a hospital submits a claim for payment, it impliedly represents that

it complied with applicable legal requirements when it provided the service. Therefore, according to the government, when a facility provides care that does not comply with the regulations and then submits a claim for reimbursement, its implied certification is false and the claim, in effect, may be fraudulent.

Court decisions on this "implied certification" theory of liability have been mixed. Many have concluded that CoPs are not the same as conditions of payment, and therefore violating CoPs is not a bar to payment on a claim or the basis for an FCA action.⁵ Others, however, have found that a fraudulent representation or promise to comply with the CoPs can indeed be the basis of a false claim.⁶

With regard to compliance with the restraint and seclusion CoP (albeit before the recent revisions), at least one hospital decided not to spend the money—or face the risk of—defending an implied certification FCA claim in court. In 2005, in order to settle an FCA claim alleging that it had improperly ordered and used physical and chemical restraints and then submitted claims for reimbursement for the service, Central Montgomery Medical Center (CMMC), while denying wrongdoing, agreed (among other terms) to pay the federal government \$200,000 and to hire a consultant to assist in the hospital's compliance with the proper ordering and use of restraints.⁷

Compliance Vulnerabilities

The revised, prescriptive CoP raises several issues where noncompliance could trigger FCA liability. Perhaps one of the most concerning areas in the revised CoP involves the definition of restraint; simply determining whether or not something is a restraint is the first step in knowing whether the CoP's remaining requirements apply. CMS attempted to clarify the definitions through extensive discussion of what constitutes a restraint in the preamble that appeared in the Federal Register when it published the regulations.⁸ CMS also held a teleconference on May 17, 2007, to clarify the provisions. Despite this, questions and judgment calls remain. For example, the preamble states that raising all four side-rails on a patient's bed is a restraint, while raising two side rails (if the bed has split side rails) generally is not. But during the teleconference, CMS stated that the presence of four raised side rails for someone recovering from anesthesia would not be a restraint, but that those same four side rails become a restraint once the patient has recovered. CMS representatives also stated that raising all four side rails based on a patient's request (for example, if the patient was afraid of falling out of bed) would constitute a restraint; but measures taken to protect patients from falling out of bed (as opposed to preventing

Continued on page 13

patients from voluntarily leaving the bed) are not restraints.

CMS representatives also stated that a drug used therapeutically in a manner approved by the Food and Drug Administration or the manufacturer or in line with national practice standards is not a restraint. However, if that same medication is used to incapacitate a patient, it becomes a restraint. Yet, drugs can be used within the manufacturer guidelines and within national practice standards, and still be used to incapacitate a patient. The vagaries in simply knowing when a restraint has occurred may result in clinicians taking an action in a good faith, believing that it is not intended as a restraint, only to be second-guessed by CMS. And, if CMS asserts that a restraint had, in fact, been used in a manner that did not comply with the CoP, will the hospital's claim for that service be rejected? If this happens regularly at a hospital, will the federal government allege false claims? What if the restraint was applied appropriately, but the care staff failed to accurately document the regular assessments? Would the entire claim be subject to scrutiny?

Other aspects of the CoP could be the focus of an FCA claim where noncompliance may be more obvious. As discussed above, the new regulation requires staff to receive specific training and be able to demonstrate competency in the "application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion" before performing any of those actions, as well as subsequently on a periodic basis. Documentation that the staff member completed that training must be in his or her personnel file. Any time a staff member implements restraints or provides care to a patient in restraints without having first received the required training and demonstrating competency, the restraint may have been applied in violation of the CoP, thus raising the risk of an FCA claim. Although it is unlikely that a single instance of noncompliance would lead to an FCA investigation, the federal government might initiate an investigation if a hospital consistently fails to ensure that its personnel received the required training.

Patient injury during restraint may be another obvious target area for

the federal government. If a patient is injured as a result of a restraint applied in a manner that is inconsistent with the new CoP, the government might refuse claims for payment for care provided to treat the injury. Although this line of reasoning has not been fully developed by the government or the courts, the time may come where any claim for payment related to iatrogenic injuries will be rejected or, possibly, deemed a false claim. Notably, the Deficit Reduction Act of 2005 requires the Department of Health and Human Services to select at least two conditions that, if not present on hospital admission, will not be subject to reimbursement. Injury associated with restraint and seclusion are not on CMS's preliminary list of conditions that the agency is considering (from which it plans to select six), leaving open the question of whether reimbursement for the costs of treating injuries associated with restraint and/or seclusion is allowed.⁹

Solutions

The best way for a hospital to avoid FCA allegations based on non-compliance with the CoPs is, of course, to maintain continual compliance with those regulations. Hospitals should act proactively to ensure that all staff are educated about the CoPs and take steps that lead to compliance and address noncompliance when it occurs. Hospital compliance programs also should be kept apprised of any failure to adhere to the CoPs and should evaluate whether noncompliance may affect the hospital's right to payment or present a risk of an FCA claim. ■

1 Title 31 U.S.C. §§ 3729-3733.

2 Title 42, C.F.R. Section 482.13(e).

3 Title 42, C.F.R., Section 482.13(e).

4 In the Federal Register, though not in the regulation itself, CMS defines LIP as "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." 71 Fed. Reg. 236, p. 71394, December 8, 2006.

5 In *United States ex rel. Mikes v. Straus*, 84 F. Supp. 2d 427, 435 (S.D.N.Y. 1999); affected by 274 F.3d 687 (2nd Cir. 2001), the court rejected the implied false certification theory of liability. Other courts that have considered the issue have mostly sided with the Straus court. *United States ex rel. Gross v. AIDS Research-Alliance-Chicago*, 415 F.3d 601 (7th Cir. 2005); *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3rd Cir. 2004); *United States ex rel. Willard v. Humana Health Plan of Tex., Inc.*, 336 F.3d 375 (5th Cir. 2003); *United States ex rel. Augustine v. Century Health Servs., Inc.*, 289 F.3d 409 (6th Cir. 2002); *In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318 (D. Conn. 2004); *United States ex rel. Barrett v. Columbia/HCA Health Care Corp.*, 251 F. Supp. 2d 28 (D.D.C. 2003); *United States ex rel. Conner v. Salina Regional Health Cir., Inc.*, F. Supp. 2d 1081 (D. Kan. 2006).

6 In *U.S. ex rel. Aranda v. Community. Psychiatric Centers, Inc.*, 945 F. Supp. 1485 (W.D. Okla. 1996), the district court allowed an implied certification claim to move forward under the FCA.

7 United States Department of Justice, Central Montgomery Medical Center Settlement Agreement, <http://www.usdoj.gov/usaof/pae/nursing/cmmccsettlementagreement.pdf> (accessed June 11, 2007)

8 71 Fed. Reg. 236, pp. 71387-71391, December 8, 2006

9 72 Fed. Reg. 85, pp. 24716-24726, May 3, 2007

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