

Restraints, Seclusion, And Patient Rights Standards For Hospitals Under The Medicare/ Medicaid Program

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I. Introduction

On July 2, 1999, the Health Care Financing Administration (“HCFA”) issued a new Condition of Participation for hospitals participating in the Medicare and Medicaid programs. Published as an interim final rule with commentary², the Condition of Participation codifies certain rights and protections for hospital patients. Not to be confused with the Consumer Bill of Rights, the Patients’ Rights Condition of Participation sets forth six (6) standards on the following patient rights: notice of rights; the exercise of patient rights; the right to privacy and safety; the right to confidentiality of patient records; the right to freedom from restraints used in the provision of acute medical and surgical care, unless clinically necessary; and, the right to freedom from restraints and seclusion used for behavior management, unless clinically necessary.

As a Condition of Participation, hospitals must meet the requirements imposed by this regulation in order to be approved for, or to continue participation in, the Medicare and Medicaid programs. Failure to comply also can result in monetary penalties and other sanctions. To enforce the regulatory provisions, HCFA will expect the State Survey Agency to determine if hospitals are in compliance. These agencies will be guided in their task by a set of interpretive guidelines, which HCFA expects to issue in the near future. Once issued, the guidelines will become a part of the HCFA State Operations Manual. These guidelines will be of assistance to hospitals in complying with the Patients’ Rights Condition of Participation.

This article presents an overview of the six standards created by the Condition of Participation, with a special emphasis on the restraint and seclusion requirements. Part II discusses the standards concerning Notice of Patient Rights, Exercise of Rights, Privacy and Safety, and Confidentiality of Patient Records. Part III addresses the impact of the Restraint and Seclusion standards.

II. Patients’ Rights Condition of Participation

A. Notice of Rights

Under this standard, a hospital is required to inform each patient (or his/her representative) of the patient’s rights, in advance of furnishing or discontinuing patient care whenever possible. The regulation does not prescribe exactly where, how, when, and by whom this notice must be made. HCFA recognizes that hospitals are of varying sizes, and serve diverse populations in a wide range of locations. Instead of imposing a single requirement for all hospitals, HCFA thus allows hospitals flexibility and creativity in implementing this standard. The interpretive guidelines, to be issued by HCFA in the near future, likely will contain additional guidance. While committed to maintaining flexibility, HCFA has commented that one method for handling some aspects of this requirement is to bundle such notices with existing

information that must be provided to patients under other Federal laws and regulations. These include regulations promulgated under Title VI of the Civil Rights Act of 1964, Section 504 of the Rehabilitation Act of 1973, and the Age Discrimination Act of 1975.

The Notice of Rights standard also requires that a hospital establish a process for the prompt resolution of patient grievances as well as inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for operation of the grievance process, although it may delegate the responsibility to a grievance committee. The regulation has set forth certain minimal requirements that must be reflected in the grievance process:

- . A clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.
- . Specific time frames for review of the grievance and the provision of a response.
- . Written notice to the patient of the resolution decision, including the name of a contact person, the steps taken to investigate the grievance, the results of the process, and the date of completion.
- . A mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Peer Review Organization.

By use of the term "Utilization and Quality Control Peer Review Organization," HCFA is referring to the State Peer Review Organizations (PROs). PROs are HCFA contractors charged with reviewing the appropriateness and quality of care rendered to Medicare beneficiaries in the hospital setting. The PRO for Virginia is the Virginia Health Quality Center. Procedures for referring Medicare beneficiary complaints to PROs already exist within hospitals. However, HCFA will expect coordination between the hospital grievance process and these existing procedures to ensure timely referral of complaints to the State PRO, when requested by the beneficiary or his/her representative.³

Although not stated in the regulation, HCFA will require that hospitals notify patients of their right to contact the State Survey Agency with a grievance, regardless as to whether the patient has first used the hospital's grievance process. HCFA also will expect that a hospital provide the patient with the address and phone number for the State Survey Agency. The Survey Agency for Virginia is the Center for Quality Health Care Services & Consumer Protection, which is an agency of the Virginia Department of Health.

B. Exercise of Rights

The Exercise of Rights standard contains four separate patient rights. A patient has the right to participate in the development and implementation of his plan of care, the right to make informed decisions, the right to formulate advance directives, and the right to have a family member or his/her own physician notified of the admission to the hospital. With regard to these rights, HCFA expects that a hospital will promote an atmosphere of two-way communication

between the patient and hospital staff and treating practitioners. The commentary to the interim rule indicates that a hospital must hold the responsible physician accountable for discussing all information regarding treatment, experimental approaches, and possible outcomes of care. The right to make informed decisions specifically includes the right to be informed of health status, the right to be involved in care planning and treatment, and the right to request and refuse treatment. HCFA declined to introduce more specific requirements for advance directives, commenting that regulations on the acknowledgment and handling of advance directives are found elsewhere in the Code of Federal Regulations.⁴

C. Privacy and Safety

Under the Privacy and Safety standard, a patient has a right to privacy, the right to receive care in a safe setting, and the right to be free from abuse and harassment. These standards are intended to protect a patient's physical and emotional health and safety. Freedom from abuse encompasses not only physical and verbal abuse but also psychological, sexual, and emotional abuse. HCFA will further elaborate on its expectations for patient privacy and safety through the interpretive guidelines. Of special note is whether the right to privacy would include a right to a private hospital room. HCFA has commented that the term "privacy" does not mean a right to a private room. However, HCFA would expect that a hospital provide some level of privacy even in semi-private rooms, i.e. pulling curtains closed for exams or requesting visitors to leave room when treatment issues are discussed.

D. Confidentiality of Patient Records

The Confidentiality standard has two specific provisions. One, a patient has the right to the confidentiality of his or her clinical records. Two, a patient has the right to access his or her records within a reasonable time frame. Under the Condition of Participation, "reasonable" access means that a hospital: (1) does not frustrate the legitimate efforts of individuals to gain access to their own medical records, and (2) actively seeks to meet these requests as quickly as possible. Rather than set precise time limits for disclosure, HCFA decided on this approach in order to account for the impact of various factors such as location of data, urgency, and staff workload. Finally, in the comment to the interim rule, HCFA notes that there may be certain extreme cases in which information can be withheld from the patient. The comment lists six circumstances that might allow the withholding of information. These circumstances include concerns that disclosure is reasonably likely to endanger the life or physical safety of the patient or another individual. In such extreme circumstances, HCFA indicates that a hospital should redact the portions to be denied, and give the patient the rest of the information.

III. Standards on Use of Restraints and Seclusion

The most controversial aspect of the Condition of Participation involves the two standards on restraint and seclusion use. The standards are a response to a public concern over injuries, accidents, and deaths resulting from restraints and seclusion. There are separate standards for the acute medical and surgical care setting and the behavior management setting. This approach is similar to the one taken by the Joint Commission on the Accreditation of Health Care Organizations.⁵ The requirements of the two standards account for the differences between interventions used for acute medical and surgical care and interventions used for behavior management. However, both are founded upon the principle that a patient has the right to be free

from seclusion and restraints, of any form, that are not medically necessary or that are used as a means of coercion, discipline, convenience, or retaliation.

Unfortunately, the regulation does not define the terms “acute medical and surgical care” or “behavior management.” HCFA also has commented that the standards are not specific to the treatment setting but rather to the situation that the restraint is being used to address. For example, an acute care hospital with a psychiatric unit would need to meet the behavior management standard for those patients. While the applicable standard for a psychiatric patient may be clearly defined, a more difficult issue for acute care hospitals will be how to characterize an application of restraints for a surgical patient who needs to be immobilized to prevent injury. In such circumstances, which standard applies? This determination is important because the behavior management standard has more stringent requirements, particularly on the timeliness of actions that must be taken by the ordering physician, than those requirements imposed by the acute medical and surgical care standard. Uncertainty as to the applicable standard will cause problems for hospitals when attempting an intervention.

The interpretive guidelines likely will provide guidance in determining which standard applies to a given situation. Until the issuance of these guidelines, HCFA’s Questions and Answers on the Patients Rights Condition of Participation provides some additional insight for acute care hospitals in particular. For the acute medical and surgical care setting, the comments and answers appear to focus upon whether an emergency situation is present. In the absence of an emergency situation, the restraint use would need to meet the criteria under the acute medical and surgical care standard.

To explain the different applications, HCFA uses the examples of surgical patients who have Alzheimer’s Diseases, Sundowner’s Syndrome⁶, or other mental impairments. One scenario uses patients that do not behave destructively or dangerously. However, the patients may have an unsteady gait or a history of wandering, and attempts to explain the situation to the patient are unsuccessful. Medical staff determine that less restrictive measures will not be effective to protect the patient. Use of a restraint in these circumstances would be governed by the acute medical and surgical care standard. This standard applies because there is nothing inherently dangerous about a patient being able to walk or wander. In contrast, HCFA offers another example of a patient who becomes agitated and aggressive and threatens the health of other patients or staff members. This behavior presents an immediate and serious danger to the safety of the patient. Use of restraint or seclusion in this situation is applied under the behavior management standard.

While apparently straightforward in its application, the behavior management standard also will present difficulties. Particularly, there is inconsistency between the underlying limitations on seclusion and restraint and a patient’s right to be free from verbal abuse. The American Psychiatric Association presented the following question to HCFA.⁷ A psychiatric patient has a manic hypersexual episode in which he is agitated and makes loud, repetitive, offensive, and lewd comments in the presence of other patients and staff. This patient poses no emergent threat to the physical safety of himself or others, so the patient cannot be restrained or secluded under the behavior management standard. However, the hospital also has the obligation to protect the right of the other patients to be free from all forms of abuse, which would include verbal abuse. This situation is yet another example of the problems that hospitals will face in implementing the restraint and seclusion standards.

The standards provide some guidance on what may constitute a restraint or seclusion by defining those terms. The restraint definition parallels HCFA nursing home requirements and the definition for seclusion follows JCAHO standards. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot remove that restricts movement or normal access to one's body. Whether a device is considered a restraint depends upon whether the patient can remove the restraint. For example, a sheet may be considered a restraint if the sheet is tucked in so tightly that the patient cannot move. Side rails that inhibit the patient's ability to get out of bed when he or she wants also constitutes a restraint. However, if the patient is able to independently remove the sheet or the side rail, then the sheet or railing does not constitute a restraint.

A drug or medication is considered a restraint if: (1) it is used to control behavior or to restrict the patient's freedom of movement; and, (2) it is not a standard treatment for the patient's medical or psychiatric condition. In addition, HCFA stresses the fundamental right of a patient to be free from restraints of any form that are imposed for coercion, discipline, convenience, or retaliation by the staff. This can be an important consideration in deciding whether to use a drug to restrain a patient. For example, HCFA explains that it would be improper for hospital personnel to administer Valium to a wandering patient simply because the staff finds his behavior bothersome. In that circumstance, the Valium is not needed for the patient's medical or psychiatric condition, and rather is administered for the convenience of the staff.

Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving. A private room would be considered seclusion if the patient is physically prevented from leaving that room. In addition, seclusion is not just confining an individual to an area, but separating him or her from others.

Both standards also have a continuing education requirement for hospital staff. The acute medical and surgical care standard simply states that all staff with direct patient contact must have ongoing education and training in the proper and safe use of restraints. The behavior management standard has more stringent requirements. Here, all staff who have direct patient contact must receive ongoing education and training in the proper and safe use of seclusion and restraint application and techniques, and alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraints or seclusion.

Finally, a hospital must report to the Health Care Financing Administration any death that occurs 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. While found in the behavior management standard, HCFA probably would expect a hospital to report as well any deaths that occur from restraint use under the acute medical and surgical care standard. This information will be used to: (1) authorize onsite investigations of hospitals in accordance with the current complaint investigation process; and, (2) inform the Protection and Advocacy entity in the respective state or territory for further action.⁸

A. Restraint Standard for Acute Medical and Surgical Care

Under this standard, restraints are permitted only if: (1) needed to improve the patient's well-being, and (2) less restrictive interventions have been determined to be ineffective.

Seclusion can never be used in the acute medical care setting. Before using a restraint, personnel must conduct a complete assessment and document the need for protective intervention with a written modification to the patient's plan of care. When assessing the patient, the hospital must determine and document that a patient has a medical condition or symptom that indicates a need for protective intervention. A fear that a patient might fall is an inadequate basis for using a restraint unless that patient has a history of falls or wandering. HCFA also expects that the medical record will contain information on less restrictive measures that were considered before the selection of restraint use.

Restraints must be ordered by a physician or other licensed independent practitioner permitted by the state and hospital to order a restraint. Orders cannot be written as a standing order or on an as needed basis. If the treating physician does not order the restraint or seclusion, the treating physician must be consulted as soon as possible.

There is no time limitation for a restraint order in the acute medical/surgical care setting. However, the regulation states that the intervention should be ended at the earliest possible time. The condition of the patient also must be continually assessed, monitored, and reevaluated. In addition, HCFA will expect that a hospital establish a policy and procedure, or issue staff guidelines, on how to determine an appropriate interval for assessment, monitoring, and reevaluation based upon the patient's needs and condition, and the type of restraint used.

B. Restraint and Seclusion Standard for Behavior Management

Restraints and seclusion can be used for behavior management only in emergency situations. An emergency is defined as: (1) when needed to ensure the patient's physical safety, and (2) less restrictive interventions have been determined to be ineffective. The medical record must document the necessity for the intervention, and that less restrictive interventions have been determined to be ineffective. As with the acute medical and surgical care setting, the intervention must be in accordance with a written modification to the patient's plan of care, implemented in the least restrictive manner, and ended at the earliest possible time.

Physicians or a licensed independent practitioner also must order the restraint or seclusion use. Again, orders cannot be written as standing orders or on an as needed basis. Understanding that a physician sometimes may be unavailable during an emergency, HCFA has commented that a hospital may develop an emergency protocol, approved by medical staff, that can be used in a manner consistent with the regulations. This protocol may allow a registered nurse to initiate an intervention based upon an appropriate assessment of the patient. In such emergent circumstances, the treating physician must evaluate, *in person*, the patient within one hour. This evaluation must be performed even if the patient quickly recovers within the one hour period. As commented by HCFA, the fact that a patient's behavior warrants the use of restraint or seclusion indicates a serious medical or psychological need for prompt assessment of the situation as well as the physiological and psychological condition of the patient.

The most controversial aspect of the behavior management standard is the introduction of mandated time limits for restraint and seclusion use. The American Psychiatric Association and the American Hospital Association, among others, have protested these requirements on the grounds that they are an inappropriate attempt to practice medicine and may substitute a practitioner's best clinical judgment.⁹

Despite such opposition, HCFA retained the following maximum time limits in the behavior management standard. A written order is limited to a maximum of 4 hours for adults, 2 hours for patients aged 9 to 17, and 1 hour for patients under 9. After this original order expires, HCFA will allow a registered nurse to examine the patient, contact the ordering physician by telephone, and report the findings from the most recent assessment. The use of the restraint or seclusion can then continue upon the physician's instructions. After the original order is continued up to a maximum of 24 hours, the physician or licensed independent practitioner must assess, in person, the patient before issuing a new order.

The behavior management standard also addresses the simultaneous use of both a restraint and seclusion. This is permitted only if the patient is continually monitored face-to-face by an assigned staff member, or continually monitored by staff using both video and audio equipment. In the latter circumstance, the monitoring must be in close proximity to the patient.

IV. Conclusion

The Patients' Rights Condition of Participation will require careful analysis on the part of hospitals to ensure that existing policies and procedures are in compliance with its directives. Hospitals also should review the interpretive guidelines, once issued, so that the hospital is in compliance with HCFA expectations. Finally, hospitals can expect further regulatory effort in these areas, especially with regard to restraint and seclusion use. HCFA has already begun considering whether to require the reporting of "serious injuries" related to restraints and seclusion, in addition to the reporting requirement for patient deaths. HCFA also is working with state and other federal agencies to determine the best system for maintaining comprehensive records of seclusion and restraints incidents.¹⁰

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² The interim final rule with commentary is published at 64 Fed.Regis. 36069-36089 (July 2, 1999)(to be codified at 42 C.F.R. § 482.13).

³ HCFA commented on this issue and other aspects of the Patients' Rights Condition of Participation in a set of Questions and Answers. These Questions and Answers can be found on the HCFA website at: <<http://www.hcfa.gov/quality/4b1.html>>.

⁴ The regulations on advance directives are found at 42 C.F.R. § 489.100 et seq..

⁵ The Joint Commission standards, for behavior management and acute medical/surgical care, can be found in the 1999 Hospital Accreditation Standards Manual (1999), Standards TX.7.1 et seq. and TX.7.5 et seq.

⁶ Sundowner's Syndrome is a condition in which the patient becomes confused and disoriented towards the end of the day. It can lead to such reactions as wandering, pacing, anger, agitation, paranoia, and violent behaviors.

⁷ See, Letter of Steven M. Mirin, M.D., Medical Director of the American Psychiatric Association, to the Health Care Financing Administration (August 28, 1999) <http://www.psych.org/pub_pol_adv/sec_res_finalcom.html>. This letter is in response to a request for comments to the interim final rule.

⁸ Protection and Advocacy Entities are authorized by Congress to access facilities and investigate abuse and neglect complaints. See, 42 U.S.C. § 10101 et seq.

⁹ See, Mirin Letter to the Health Care Financing Administration. See also, "AHA Seeks to Loosen Restraint Rules as Attorneys Warn of Compliance Problems," 8 BNA Health Law Reporter 1402, 1405 (August 26, 1999).

¹⁰ See, The Importance of Preventing Inappropriate Use of Seclusion and Restraints in Psychiatric Treatment Facilities: Hearings Before the Senate Finance Committee on Patient Treatment in Mental Hospitals, (October 26, 1999)(testimony of Michael Hash, Deputy Director, HCFA) <<http://www.hcfa.gov/testmony/1999/991026.html>>.