Medical Education Systems, Inc.

Course 901

Restraints, Seclusion and Patient Rights Under Medicare/Medicaid

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

Learning Objectives

Upon successful completion of this course, you will be able to:

- Define the terms “restraints” and “seclusion” in the healthcare setting
- Identify the key elements of HCFA’s Patients' Rights Condition of Participation
- Explain the minimal requirements that must be reflected in any patient-hospital grievance process
- List and discuss the “standards on use of restraints and seclusion” set forth by HCFA

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 commentary, 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 are guided in their task by a set of interpretive guidelines. The guidelines have become a part of the HCFA State Operations Manual. These guidelines are intended to be of assistance to hospitals in complying with the Patients' Rights Condition of Participation.

This course 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.

- 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 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.

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 further elaborates 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 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.

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.

HCFA's Questions and Answers on the Patients Rights Condition of Participation provides some additional insight for acute care hospitals in particular provide guidance in determining which standard applies to a given situation. 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 Syndrome, 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.

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 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.

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.

According to 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.

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.

Aside from HCFA's guidelines, numerous organizations and hospitals (of course) have established their own guidelines that should be reviewed as you learn about these important patient rights. **We offer some of those for your examination here:**

The American College of Emergency Physicians (ACEP)
Use of Patient Restraints

Approved by the ACEP Board of Directors April 2001. This statement replaces one with the same title approved by the ACEP Board of Directors, June 2000.Replaced with policy statement with the same title and approved by the ACEP Board of Directors January 1996

The American College of Emergency Physicians (ACEP) supports the careful and appropriate use of patient restraints or seclusion. ACEP recognizes that patient restraint involves issues of civil rights and liberties, including the right to refuse care, freedom from imprisonment, and freedom of association. However, there are circumstances when the use of restraints is in the best interest of the patient, staff, or the public.

Methods of patient restraint include physical restraints, chemical restraints, and seclusion. Patient restraint should be considered when a careful assessment establishes that the patient is a danger to self or others by virtue of a medical or psychiatric condition.

ACEP endorses the following principles regarding patient restraints:

- Restraints should be individualized and afford as much dignity to the patient as the situation allows.
- Any restraints should be humanely and professionally administered.
- Protocols to ensure patient safety should be developed to address observation and treatment during the period of restraint and periodic assessment as to the need and means of restraint.
- The use of restraints should be carefully documented. Such documentation should include the reasons for and means of restraint and the periodic assessment of the restrained patient.

- The method of restraint should be the least restrictive necessary for the protection of the patient and others.
- ACEP opposes any requirement by hospital representatives or medical staffs that emergency physicians provide inpatient restraint or seclusion orders. Patient restraint or seclusion requires comprehensive patient assessment, [1] and the emergency physician's principal legal and ethical responsibility is to patients who present to be seen and treated in the emergency department. [2]
- The use of restraints should conform to applicable laws, rules, regulations, and accreditation standards.

References

1. 42 CFR 482.13(f).
2. American College of Emergency Physicians. Emergency physicians' patient care responsibilities outside of the emergency department [policy statement];Approved September 1999. Ann Emerg Med 2000;35:209.

The American Academy of Physician Assistants position paper on the HCFA guidelines:

Patients' Rights: Restraint and Seclusion

Recent patient deaths resulting from inappropriate restraint techniques have focused public attention on the use of restraints in institutional care. Some advocacy groups recommend that seclusion and restraint be completely eliminated. Health care providers, particularly those in emergency departments and mental health settings, argue that in some situations seclusion and restraint are necessary components of treatment for individuals who are threatening immediate harm to themselves or others.

The AAPA opposes inappropriate use of restraint or seclusion. Academy policy states, "The American Academy of Physician Assistants believes that patients have the right to be free of all forms of seclusion and physical and chemical restraint that are not medically necessary. Seclusion and restraint should not be used as a means of coercion, discipline, convenience, or retaliation. Seclusion and restraint should only be used according to accepted medical standards for the purpose of protecting the patient or others and to improve a patient's functional well being and only if less intrusive interventions have been determined to be ineffective."

Language chosen by both the Health Care Financing Administration(HCFA) and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to limit the use of restraints and seclusion has been problematic for some PAs and physicians. Both HCFA regulations and JCAHO standards state that restraint or seclusion use must be ordered by a physician or other "licensed independent

practitioner." Although this language appears to prohibit physicians from delegating these tasks to physician assistants, both organizations state that is not their intent. Indeed, both organizations state that physicians may delegate this to the extent allowed by state law and institutional policy.

In addition, the National Alliance for the Mentally Ill (NAMI), a nonprofit, grassroots, self-help, support and advocacy organization of consumers, families, and friends of people with severe mental illnesses, such as schizophrenia, major depression, bipolar disorder, obsessive-compulsive disorder, and anxiety disorders has issued its position paper:

Seclusion and Restraint

NAMI's Position ***(summarized from the NAMI Policy Platform)***

The use of involuntary mechanical or human restraints or involuntary seclusion is only justified as an emergency safety measure in response to imminent danger to a patient or others. These extreme measures can be justified only so long as, and to the extent that, an individual cannot commit to the safety of him or her-self and others.

Restraint and seclusion have no therapeutic value and should be used only for emergency safety by order of a physician with competency in psychiatry or a licensed independent mental health professional (LIP). A physician trained in psychiatry or a LIP should see the patient within one hour after restraints are initiated. Restraints should be continued only for periods of up to one hour at a time, and a face-to-face examination of the patient by the physician or LIP must occur prior to each time a restraint order is renewed.

Alternatives to the use of restraint and seclusion should be used. De-escalation techniques and debriefings should be used after each restraint and seclusion incident.

The Media: A Clear Pattern of Abuse Exposed

In October 1998, *The Hartford Courant* published a five-part investigative series that revealed an alarming number of deaths resulting from the inappropriate use of physical restraints in psychiatric treatment facilities across the United States. A 50-state survey conducted by the newspaper documented at least 142 deaths in the past decade connected to the use of physical restraints or to the practice of seclusion. The report also suggested that the actual number of deaths is many times higher because many incidents go unreported. According to a separate statistical estimate commissioned by *The Courant* and conducted by the Harvard Center for Risk Analysis, between 50 and 150 restraint- or seclusion-related deaths occur every year across the country.

As a result of *The Hartford Courant* series and NAMI's communications with its members, NAMI members have shared their horror stories of abuse and death. These are compiled in NAMI's report, *Cries of Anguish*. More than 60 personal stories of incidents from 24 states and the District of Columbia were reported as of August 2000.

Understanding the Issue

Restraints are human or mechanical actions that restrict freedom of movement or normal access to one's body. Since the development of more effective psychotropic medications, emergency situations have become increasingly rare. In fact, some hospitals have moved to restraint-free policies.

In current practice, physical restraints are sometimes imposed on a patient involuntarily for **control of the environment** (curtailing individual behavior to avoid the necessity for adequate staffing or clinical interventions); **coercion** (forcing the patient to comply with the staff's wishes); or **punishment** (staff punishing or penalizing patients). NAMI rejects these as legitimate reasons to impose restraints.

Federal Protections Enacted in 2000

In October 2000, President Clinton signed the Children's Health Act of 2000, P.L. 106-310. This significant new law established national standards that restrict the use of restraint and seclusion in all psychiatric facilities that receive federal funds and in "non-medical community-based facilities for children and youth."

NAMI will be following the implementation of key provisions under the general requirements, which include:

> Restraints and involuntary seclusion (R/S) may only be imposed to ensure the physical safety of a patient. They cannot be used as punishment or for staff convenience.

R/S may be imposed only under the written order of a physician or other licensed practitioner permitted to issue such orders under state law. Orders must specify the duration of and circumstances for the R/S.

Although no timeframe is specified for conducting face-to-face evaluations of patients who have been or will be restrained or placed in seclusion, the legislation declares that the lack of a specified timeframe should not be interpreted as offsetting or impeding any federal or state regulations that provide greater protections for patients. This declaration then affirms hospital rules promulgated last year by the Health Care Financing Administration (HCFA) including the "one hour rule" that requires face to-face evaluations by licensed professional practitioners within one hour of initiating R/S.

Facilities must report every death that occurs within 24 hours after a patient has been removed from R/S or where it is reasonable to assume that a death is the result of R/S. Reports must be made to agencies determined appropriate by the Department of Health & Human Services (HHS), which most likely will include state protection and advocacy agencies.

Within 12 months, HHS also must issue regulations specifying adequate numbers of staff for facilities and appropriate training for the use of R/S and its alternatives.

For children's non-medical community programs:

R/S may be used with children in community programs only in emergencies and to ensure immediate physical safety for the child or others. Mechanical restraints are prohibited. Seclusion is allowed only when a staff member continuously monitors a child face-to-face. Time-outs, however, are not considered seclusion, and physical escorts are not considered physical restraints.

Only individuals trained and certified by a state-recognized body may impose R/S. Until a state certification process is in place, R/S can be used only when a supervisory or senior staff person with skills and competencies specifically listed in the legislation conducts a face-to-face assessment of the child within an hour after R/S is imposed. The use of R/S must then be monitored by the supervisory or senior staff person.

Required skills and competencies include an understanding of the needs and behaviors of the populations served, relationship-building, avoiding power struggles, de-escalation methods, alternatives to R/S, time limits, monitoring signs of physical distress, position asphyxia, obtaining medical assistance, and familiarity with relevant legal issues.

Within six months, states (which license such facilities) must develop licensing and monitoring rules and HHS will begin to develop national staffing standards and guidelines.

These R/S standards apply only to psychiatric treatment facilities that receive federal funding. They do not affect use of restraint and seclusion in schools, wilderness camps, jails, or prisons. P.L. 106-310 also does not impede any federal or state laws or regulations that provide greater protections than written in the Children's Health Act of 2000. Thus, rules issued by the Health Care Financing Administration in 1999 that included a requirement for face-to-face evaluations by mental health professionals within one hour of initiating restraint are affirmed.

NAMI's Advocacy Goals and Strategies

NAMI strongly supports full implementation of the restraint and seclusion provisions included in P.L 310-106;

NAMI will monitor the progress of the Department of Health and Human Services in issuing national guidelines and regulations specifying adequate number of staff in facilities and appropriate training in the use of R/S and their alternatives;

NAMI will also advocate for a national standard in schools, wilderness camps, jails, and prisons

What Should You Do If You Experience Restraint And Seclusion Abuse?

If you or your family member has experienced abuse of R/S in a treatment facility, you should take the following action.

Contact your state's Protection and Advocacy program. For the phone number of your state's program, call the National Association of Protection and Advocacy Systems (NAPAS) at 202-408-9514. If a P & A does not assist you, let NAMI know by contacting Kim Encarnation at 703-312-7895 or by email at kim@nami.org.

File a complaint with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) hotline at 1-800-994-6610 and/or complaint@jcaho.org

File a complaint with your state's health and hospital-licensing agency.

File a complaint with your U.S. Health Care Financing Administration (HCFA) regional office. There are 10 regional offices in the United States. To find yours, call the HCFA Medicare Hotline, 1-800-638-6833. You can also call the HCFA Office of Medicare Customer Assistance, 410-786-7413.

Share your story in writing and submit it to be included in NAMI's *Cries of Anguish* report. Contact Kim Encarnation at 703-312-7895 or kim@nami.org

Consider sharing your story with your local media.

Consider retaining an attorney if you believe your legal rights have been violated

The Mental Health Legal Advisors Committee has also put out their perspective on how guidelines relating to restraints and seclusion should be structured:

RIGHTS IN HOSPITALS REGARDING

RESTRAINT AND SECLUSION

Hospitals may use restraint and seclusion only in cases of emergency and in compliance with strict standards. Additional requirements, not included here, apply when restraining children.

I. WHAT IS RESTRAINT?

"Restraint" is physical force, mechanical devices, chemicals, seclusion, or any other means which unreasonably limit freedom of movement. Hospital staff may use four types of restraint to restrict patients who are acting, or threatening to act, in a violent way towards themselves or others.

- **Physical restraint --** holding a patient in a way that restricts his or her movement.

- **Mechanical restraint --** using a device, such as four-point or full-sheet restraint, to restrict a patient's movement (excludes devices prescribed for medical purposes).

- **Chemical restraint --** medicating a patient against the patient's will for the purpose of restraint rather than treatment.

- **Seclusion --** placing a patient alone in a room so that the patient cannot see or speak with patients or staff *and* so that the patient cannot leave or believes he or she cannot leave. In facilities licensed, operated, or contracted for by the state Department of Mental Health (DMH), a mechanically restrained patient cannot be secluded.

II. WHEN MAY RESTRAINT BE USED?

Restraint may only be used to prevent violence in an **emergency.** An emergency is the ***occurrence of or serious imminent threat of extreme violence or self-destructive behavior,*** "where there is the present ability to effect such harm." Restraint may *not* be used for treatment, punishment, behavior modification, staff convenience or on an "as needed" basis (PRN orders). Restraint must be the most appropriate alternative available. Restraint may only be used when less restrictive interventions have been determined to be ineffective.

III. WHO MAY ORDER RESTRAINT?

Mechanical restraint, physical restraint and seclusion require written orders by **an authorized physician or other licensed independent practitioner permitted by the state and hospital to order a restraint.** If the physician or other qualified practitioner is unavailable, a designated staff person may authorize restraint for no more than one hour. A physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within one hour after the initiation of the intervention. These orders may be renewed only to prevent a continued or renewed emergency. Only an **authorized physician** may order *chemical restraint,* but he or she may issue the order over the telephone by speaking to a registered nurse or certified physician's assistant who has personally examined the patient. A physician may only order chemical restraint if the medication has been previously authorized in the patient's treatment plan. Furthermore, chemical restraint may only be administered if it is the least restrictive, most appropriate alternative available. The treating physician must be consulted as soon as possible, if he or she does not order the restraint.

IV. HOW LONG MAY RESTRAINT CONTINUE?

When an emergency no longer exists, the patient must be released. Thus, staff should release a patient who, upon examination, appears calm. The total time which a patient may be restrained is limited:

- An initial restraint or seclusion order is valid for three hours.
- After three hours, a superintendent, authorized physician, registered nurse, or certified physicians assistant may continue restraint or seclusion if the emergency still exists.
- After six hours, an authorized physician must examine the patient and renew the order.
- The maximum amount of restraint or seclusion allowed is eight hours in any 24-hour period unless the superintendent or his or her designee so authorizes.

V. WHAT FURTHER PROTECTIONS EXIST FOR RESTRAINED PATIENTS?

A patient in a facility operated by DMH, contracted for by DMH, or licensed by DMH has additional rights:

- The patient must be fully clothed consistent with patient safety and dignity;
- The patient must have access to the bathroom;
- The patient should be continually assessed by staff to determine if the restraint or seclusion is still needed. These checks must be made at least once every 30 minutes;
- Any space or device used must provide appropriate and safe ventilation, heating and lighting;
- Once restrained or secluded, staff should help the patient calm down by using appropriate interventions; and
- Staff must determine if the patient has a history of abuse by gathering information during intake from the patient, the patient's record, and, when necessary, from other treating clinicians. If the patient has an abuse history, staff will use strategies to help reduce

the patient's agitation so as to avoid the need for restraint. If restraint or seclusion is necessary, staff must determine which type will be the least traumatic for the patient and which gender of staff would be most appropriate to administer or monitor it.

Furthermore, a patient in a DMH-*operated* facility has these additional rights:

- To avoid restraint, staff should attempt to calm the patient through talking and other non-violent means;
- The attendant accompanying the patient to the bathroom should be of the same sex as the patient;
- A patient may not be held in restraint or seclusion for more than one-half hour without a break unless he or she poses a violent threat to self or others (or is asleep);
- A patient who is quiet must be released for a trial period; and
- Staff should experience restraint as part of their training.

VI. WHAT ARE THE OBSERVATIONAL REQUIREMENTS FOR RESTRAINT?

When a patient is restrained or secluded, a specially trained person must be able to observe the patient. The condition of the patient in restraint must continually be assessed, monitored, and re-evaluated.

During *seclusion,* the observer may be immediately outside the patient's room--provided that the patient can fully see staff and staff can continuously observe the patient.

All staff who have direct patient contact must have ongoing education and training in the proper and safe use of restraint application and techniques and alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraints.

In facilities licensed, operated, or contracted for by DMH, staff must check a patient in mechanical restraint or seclusion every 15 minutes for comfort, body alignment and circulation.

VII. WHAT DOCUMENTATION IS NECESSARY FOR RESTRAINT?

- Each time restraint is ordered or renewed, the authorizer must record the reason for its use on a form.
- Within 24 hours of being restrained, the patient must receive a copy of the restraint form and be permitted to attach comments concerning the use of restraint.
- The form and the patient's comments must be placed in the patient's chart and a copy sent to the Commissioner of DMH, who must review and sign them within 30 days.
- The hospital must report to the federal Health Care Finance Agency 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 and seclusion.

VIII. WHAT SHOULD YOU DO IF YOU BELIEVE YOU HAVE BEEN ILLEGALLY RESTRAINED?

If you believe that you were illegally restrained while at a program or facility operated by, contracted for, or licensed by DMH, ask to speak with the Human Rights Officer. You may also file a written **complaint** with the Person in Charge of the program or facility. You can give your complaint to any facility employee; he or she must forward it to the Person in Charge. If you are dissatisfied with the response of the Person in Charge and believe that additional fact-finding should occur, you have 10 days to request **reconsideration.** You also may file an **appeal** to a higher level up to 10 days after receiving a decision. The person to whom the appeal is made depends upon the type of complaint and the type of facility. In most cases, you have the right to a **further appeal,** which must be filed within 10 days of receiving the appeal decision. If you have questions about the complaint process, contact the Human Rights Officer or the Mental Health Legal Advisors Committee (1-800-342-9092).

Mental Health Legal Advisors Committee, 294 Washington Street, Suite 320,Boston, MA 02108--(617) 338-2345--(800) 342-9092

The last sample position paper on the use of restraints and seclusion we would like you to review is that of the American Nurses' Association:

Effective Date: October 17, 2001
Status: Position Statement
Originated By: Congress on Nursing Practice and Economics
Adopted By: ANA Board of Directors

Reduction of Patient Restraint and Seclusion in Health Care Settings

Summary: Dilemmas in patient care situations are an inevitable consequence of professional accountability. With regard to use of restraints, nurses struggle with conflicts stemming from patients' rights of freedom, nurses' feelings of obligation to "protect" patients, and family and peer pressure to use restraints. ANA believes ***only when no other viable option is available should restraint be employed***. In those instances where restraint, seclusion or therapeutic holding is determined to be "clinically appropriate and adequately justified," registered nurses, who possess the necessary knowledge and skills to effectively manage the situation, must be actively involved in the assessment, implementation and evaluation of the selected intervention.

Background

Nursing has a history of being involved with attempts at reduction in the use of restraint going back well over one hundred years. Frequently, when restraint was employed it was in the belief that such action would promote patient safety. It was this belief, in part, which led to the increase in restraint use in the nursing home population. As concern about the quality of patient care in that setting rose the Nursing Home Reform Act (a part of the Omnibus Reconciliation Act of 1987) was adopted into law. The results of this law, which greatly affected the quality of care received through increased assessment of and care planning for the patient as well as through reduction of both physical and chemical restraint, have implications for individuals with mental illness as well. The patient populations affected are the elderly, psychiatric patients (adults and children) and disoriented or physically aggressive patients. The settings of restraint use include: psychiatric facilities and residential sites for those with mental illness, developmental or behavioral problems; general hospitals, emergency departments, nursing homes (Sullivan-Marx and Strumpf, 1996).

Definitions:

Restraint is...

> ***any involuntary method (chemical or physical) of restricting an individual's freedom of movement, physical activity, or normal access to the body.***

chemical restraint:

The use of a sedating psychotropic drug to manage or control behavior. Psychoactive medication used in this manner is an inappropriate use of medication.

physical restraint:
The direct application of physical force to a patient, without the patient's permission, to restrict his or her freedom of movement (JCAHO, 2000).

The physical force may be human, mechanical devices, or a combination thereof. This definition does not apply to (1) interactions with patients that are brief and focus on redirection or assistance in activities of daily living, such as hygiene and (2) the use of any psychoactive medication that is a usual or customary part of a medical diagnostic or treatment procedure, and that is used to restrict a patient's freedom of movement (JCAHO, 2000).

Seclusion refers to...

> ***the involuntary confinement of a person in a locked room*** (JCAHO, 2000).

Therapeutic holding is...

> ***the physical restraint of a child by at least two people to assist the child who has lost control of behavior to regain control of strong emotions*** (American Academy of Pediatrics, 1997).

In the past, when restraint was employed it was in the belief that such action would promote patient safety and without effective restraint and seclusion practices, patients were considered to be in danger of injuring themselves or others, including nursing staff, or being injured by other assaultive patients. The danger of employing such restraint, however, has been demonstrated to be problematic. There is a need for additional research to explore patient safety factors related to restraint and seclusion and the role of the registered nurse in their elimination.

A 50-state survey by a Connecticut newspaper (*Hartford Courant 1998*), revealed at least 142 deaths related to the use of physical restraint or seclusion since 1988. The report also noted that the true number of deaths is much higher since data about many such deaths is not public information. In one case, a patient at Virginia's Central State Hospital died after being restrained for 300 hours, including two intervals of approximately 110 hours each. Young men in a residential treatment facility in Pennsylvania and at a private psychiatric hospital in North Carolina died shortly after being physically restrained by personnel who were caring for them. According to statistical projections commissioned by *The Courant* and conducted by the Harvard Center for Risk Analysis, between 50 and 150 such deaths occur every year across the country due to improper restraint procedures. The National Alliance for the Mentally Ill (NAMI, 1999) has received reports from fifteen states about 24 incidents related to the use of restraints and/or seclusion, ranging from a sixteen year old in California who died while restrained by four staff members to an Ohio man who died in restraints running a temperature of 108 degrees. Situations

such as these cannot be allowed to continue. There is a critical need for mandated monitoring of the use (frequency, methods etc.) of restraint and seclusion.

ANA supports the rights of patients of all ages and in all settings to be treated with dignity, concern and to receive safe, quality care. Developmentally appropriate methods of restraint must be used in the least restrictive manner. The family members, guardians or significant others of individuals placed in restraint must be informed immediately.

ANA recognizes that seclusion and/or restraint may be more likely to be employed inappropriately—that is, for non-emergency situations and/or for circumstances where no significant risk of harm exists—when hospital unit staffing is inadequate or staff are inappropriately trained to provide less restrictive interventions. Where the hospital cannot provide for an assessment by a physician or other appropriately licensed health care professional within an hour, ANA supports that all the following requirements should apply: (1) a registered nurse shall confer by telephone with a physician or other health care professional permitted by the State and hospital to order restraint or seclusion within an hour after the restraint or seclusion is initiated. (This requirement is also consistent with ANA's proposal on obtaining telephone orders within an hour after instituting the procedure if an order cannot be obtained beforehand). (2) The reasons for a patient not being seen within the hour shall be documented in the patient record. (3) The patient must be physically assessed by a registered nurse hourly until a physician or other appropriately licensed health care professional arrives to see the patient. (4) The patient must be seen by an RN or physician or other health care professional permitted by the State and hospital to order restraint or seclusion within one hour after being placed in restraint or seclusion. Adding such language to the current requirements assures that the patients' safety is not compromised by delay in assessment.

To achieve reduced restraint care, formal mission statements and policies that clearly state the intent to promote a reduced restraint environment for patients must be adopted. Such statements must include a focus on: 1) intention to comply with policy standards; 2) environmental designs to facilitate restraint reduction; and 3) implementation of an individualized approach grounded in the following principles: 1) all behavior has meaning; 2) patient needs are best met when behavior is understood; and 3) a systematic approach of assessment, intervention, and evaluation is the best means to respond to behavior.

When instituting change toward reduced restraint care, initial educational efforts must address fundamental components of such care. Open communication and dialogue at board and highest administrative levels, and including staff from all disciplines, as well as community representatives, and staff are essential to implementing change. Early success with less complex problems, such as eliminating restraints for positional support with substitution of wedge or roll cushions, fosters confidence for handling more difficult situations. If systems lack internal resources to provide education and specialist intervention, independent nursing consultation services can be contracted to provide for these needs.

Targeting specific units or groups of patients, such as all new admissions, and then identifying those who are restrained (and why) lays the groundwork for interventions aimed at eliminating

restraints. Interventions may take the form of actions categorized as pharmacologic, physiologic, psychosocial, activity or environment.

Physiologic approaches include such efforts as pain relief, comfort measures, or investigating symptoms indicative of developing complications, such as hypoxia or fever. Psychosocial interventions focus on the meaning of patient behavior and address that need, e.g. is the agitated patient fearful of impending surgery? Activities can include talking with the patient, physical exercise/therapy, involvement in activities, meaningful distraction, or contact with familiar persons or places, even by telephone. Environmental adjustments may range from simple use of light to facilitate vision, relocation of the patient to another bed or room, to specifically designed units that reduce the hazards of falling. To foster transition to reduced restraint care and sustain lasting change beliefs must be altered and knowledgeable practice enhanced through education, intensive clinical evaluation, and consistent reinforcement of standards and policy (Sullivan-Marx and Strumpf, 1996).

Finally, it must be recognized that psychotropic medications are not merely ‘chemical restraints' but treatment strategies which can result in a decreased need for therapeutic holding and/or physical restraint. However, there must be an adequate number of professional nurses available to provide the necessary care. Staff must be educated in the use of alternatives to restraint and such alternatives must be made available to them both through organizational policy and in fact. Only then, can the safety and quality of patient care be assured.

There is a critical need to provide educational opportunities for nurses to assist them to develop the necessary assessment and intervention skills to prevent the need for restraint and seclusion ANA is concerned that lack of personnel to provide adequate monitoring of patients and less restrictive approaches to behavior management may place patients at greater risk of violation of their rights and of harm caused by being placed in seclusion and/or restraints.

References

American Academy of Pediatrics, Committee on Pediatric Emergency Medicine (1997). The use of physical restraint interventions for children and adolescents in the acute care setting (RE9713). *Pediatrics*, 99(3).

American Nurses Association. (2001) *Code of Ethics for Nurses with Interpretive Statements*. Washington, DC: American Nurses Publishing.

American Psychiatric Nurses Association. (2000). *Position Statement on the Use of Seclusion and Restraint*. Washington, DC: Author.

Health Care Financing Administration. (2000, January). *Quality Standards: Patients' Rights Conditions of Participation*. <http://www.hcfa.gov/quality/4b.htm>.

International Society of Psychiatric-Mental Health Nurses. (1999). *A Position Statement on the Use of Restraint and Seclusion*. Philadelphia: Author.

Joint Commission on the Accreditation of Healthcare Organizations. (2000). *Automated Comprehensive Accreditation Manual for Behavioral Health Care*. Oakbrook Terrace, IL: Author.

Maier, G.(1996). Managing threatening behavior: The role of talk down and talk up. *Journal Psychosocial Nursing*, 34,25-30.

National Alliance for the Mentally Ill. (1999, October). *CRIES OF ANGUISH: A Summary of Reports of Restraints & Seclusion Abuse Received Since the October 1998 Investigation by The Hartford Courant*. <http://www.nami.org/update/hartford.html>.

Occupational Safety and Health Administration. (1998). *Guidelines for preventing workplace for health care and social service workers*. (OSHA Publication No.3148). Washington, DC: Author.

Strumpf, N. & Tomes, N. (1993). Restraining the troublesome patient. a historical perspective on a contemporary debate. *Nursing History Review*, 1, 3-24.

Sullivan-Marx, EM and Strumpf, NE. (1996). Restraint-free care for acutely ill patients in the hospital. *AACN Clinical Issues: Advanced Practice in Acute and Critical Care*. 7(4), 572-573.

Weiss, E. (1998, October). "Deadly Restraint: A nationwide pattern of death". *The Hartford Courant*.

Examination

Select the ***best*** answer to each of the following items. Mark your responses on the Answer Form.

1. The Patients' Rights Condition of Participation six (6) standards include which of the following:

a. notice of rights
b. right to privacy and safety
c. the right to freedom from restraints and seclusion used for behavior management, unless clinically necessary
d. All of the above

2. According to HCFA, 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.

a. True
b. False

3. HCFA stresses the fundamental right of a patient to be free from restraints of any form that are imposed for _____ , or retaliation by the staff.

a. coercion
b. discipline
c. convenience
d. All of the above

4. 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.

a. True
b. False

5. Whether a device is considered a restraint depends upon whether _____.

a. it contains any "inter-locking" parts
b. it prevents certain movements
c. the patient can remove the restraint

d. All of the above

6. 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.

a. True
b. False

7. Both standards (on restraints and on seclusion) have a _____ requirement for hospital staff.

a. self-reporting
b. continuing education
c. punishment for failure to comply
d. All of the above

8. A sheet may be considered a restraint if the sheet is tucked in so tightly that the patient cannot move.

a. True
b. False

9. Under the Restraint Standard for Acute Medical and Surgical Care, 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.

a. True
b. False

10. Restraints must be ordered by a physician or _____ permitted by the state and hospital to order a restraint.

a. intern
b. surgeon
c. other licensed independent practitioner
d. None of the above

11. 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.

a. True
b. False

12. 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.

a. True
b. False

13. 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. True
b. False

14. 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.

a. True
b. False

15. Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.

a. True
b. False

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