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RESTRAINT AND SECLUSION

I. INTRODUCTION

The use of restraint and seclusion in health care facilities is highly regulated by both the state and federal government. In the year prior to the publication of the Centers for Medicare & Medicaid Services (CMS) interim final rule regarding patient rights in 1999, the public, patient advocacy groups, the media and Congress became increasingly concerned about the need to ensure basic protections for patient health and safety in hospitals with regard to the use of restraint and seclusion. The *Hartford Courant*, a Connecticut newspaper, heightened public awareness of this issue with a series of articles in October 1998 citing the results of a study that identified 142 deaths from seclusion or restraint use in mental health treatment facilities in the previous 10 years. The majority of the deaths were adolescent patients. The *Hartford Courant* articles were reprinted around the country, receiving widespread attention and leading to broad criticism of both private hospital accreditation organizations and government agencies charged with oversight of patient protection and safety.

The goal of the laws regarding restraint and seclusion is to protect patients' rights to be free from the inappropriate use of restraint and seclusion; to protect the patient, hospital staff, and others from violent or self-destructive behavior; and to promote patient safety when the use of either intervention is necessary.

A. SCOPE OF CHAPTER

This chapter addresses all state and federal laws regarding restraint and seclusion applicable to general acute care hospitals (GACHs) and acute psychiatric hospitals (APHs) with respect to mental health patients.

This chapter does not discuss all laws regarding restraint and seclusion applicable to skilled nursing facilities, intermediate care facilities, psychiatric health facilities (PHFs) or psychiatric residential treatment facilities. In addition, hospitals operated by the state of California or the United States government may be subject to additional requirements not described in this chapter.

B. RESTRAINT AND SECLUSION LAWS

FEDERAL LAW

CMS Conditions of Participation and Interpretive Guidelines

The primary federal law regarding restraint and seclusion is found in the regulation published by CMS as part of the

Patients' Rights Condition of Participation (CoP) [42 C.F.R. Section 482.13]. All hospitals (acute care, long-term care, psychiatric, children's, and cancer) must comply with the regulation to participate in the Medicare and Medicaid programs. The requirements of the regulation apply to all patients in a Medicare- or Medicaid-participating hospital, not just Medicare or Medicaid beneficiaries. The requirements apply to inpatients and outpatients in all locations within the hospital (including medical/surgical units, critical care units, emergency department, psychiatric units, etc.). However, critical access hospitals must comply only if they have a distinct-part psychiatric or rehabilitative unit.

CMS contracts with "State Survey Agencies" (SAs) to survey hospitals to assess their compliance with the CoPs. In California, the SA is the California Department of Public Health (CDPH). The SAs conduct these surveys using the *State Operations Manual* (SOM) published by CMS. The SOM contains the actual language of the regulation as well as *Interpretive Guidelines* and survey probes that elaborate on regulatory intent and give in-depth detail to surveyors and hospitals about how to determine compliance with the CoPs. The SAs determine whether hospitals meet the CoPs.

This chapter discusses the requirements of the CMS CoP/ regulation related to restraint and seclusion, and describes the *Interpretive Guidelines*, including survey probes to describe what surveyors will look for during surveys.

Children's Health Act of 2000

A federal statute, the Children's Health Act of 2000 (Pub.L. 106-310), was enacted on Oct. 17, 2000 — after the publication by CMS of its interim final rule regarding restraint and seclusion, but before publication of the final rule.

The Children's Health Act contained several provisions not specific to children's health, including some related to restraint and seclusion [42 U.S.C. Sections 290ii to 290ii-2]. CMS incorporated these statutory requirements into its final rule, which amended the hospital CoPs, regarding restraint and seclusion. Therefore, hospitals in compliance with the CoPs are also in compliance with the Children's Health Act requirements related to restraint and seclusion.

Noncompliance with one or more CoPs or the restraint and seclusion provisions of the Children's Health Act may lead to termination from the Medicare and Medicaid programs.

CALIFORNIA LAW

The primary law in California regarding restraint and seclusion is found in Health and Safety Code Sections 1180.1 to 1180.4. This statute applies to patients admitted to acute

psychiatric hospitals and to psychiatric units of general acute care hospitals (and other facilities as well). It does not apply to patients in a medical/surgical unit, an ICU, or the emergency department of a general acute care hospital.

Hospital licensing regulations (Title 22) also contain several requirements regarding the use of restraint and seclusion. They are included in this chapter.

MUST COMPLY WITH ALL LAWS

California hospitals that participate in Medicare or Medicaid programs must comply with all of the federal requirements and all of the state requirements described in this chapter. There is no federal preemption of state law.

C. ACCREDITATION ORGANIZATION STANDARDS

California hospitals that are accredited by The Joint Commission (TJC) or other accreditation organizations must comply with the standards established by those organizations. As of the date of publication of this manual, TJC standards regarding restraint and seclusion were identical to the federal law requirements described in this chapter; therefore, compliance with the requirements described in this chapter will ensure compliance with TJC standards. (The relevant TJC standards are PC.03.05.01 through PC.03.05.19.)

Other accrediting organizations may have adopted different requirements regarding the use of seclusion or restraint. Hospitals accredited by organizations other than TJC should carefully check those requirements in addition to complying with the requirements described in this chapter.

II. PATIENTS' RIGHTS REGARDING RESTRAINT AND SECLUSION

Both state and federal law contain multiple provisions regarding patients' rights. Requirements regarding patient rights in general — that is, rights that apply to all patients, not just mental health patients — are described in chapter 1 of CHA's *Consent Manual*. Requirements regarding the general rights of mental health patients are described in chapter 4 of this manual. This chapter describes only those patients' rights that are specific to restraint and seclusion.

A. FEDERAL LAW: CMS CONDITIONS OF PARTICIPATION AND INTERPRETIVE GUIDELINES

Federal law states that all patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may be imposed only to ensure the immediate physical safety of the patient, a staff member, or others and must be

discontinued at the earliest possible time. The patient also has the right to safe implementation of restraint or seclusion by trained staff [42 C.F.R. Section 482.13(e) and (f)].

The *Interpretive Guidelines* state that hospital leadership is responsible for creating a culture that supports a patient's right to be free from restraint or seclusion. Leadership must ensure that systems and processes are developed, implemented, and evaluated that support patients' rights and that eliminate the inappropriate use of restraint or seclusion. Through its Quality Assurance/Performance Improvement (QAPI) program, hospital leadership should:

1. Assess and monitor the use of restraint or seclusion in the facility;
2. Implement actions to ensure that restraint or seclusion is used only to ensure the physical safety of the patient, staff and others; and
3. Ensure that the hospital complies with the requirements set forth in the federal regulation as well as those set forth by state law and hospital policy when the use of restraint or seclusion is necessary.

SURVEY PROCEDURES

The *Interpretive Guidelines* direct surveyors to consider the following:

1. Review a sample of medical records of patients for whom restraints were used to manage non-violent, non-self-destructive behavior, as well as a sample of medical records of patients for whom restraint or seclusion was used to manage violent or self-destructive behavior;
2. Include in the review patients who are currently in restraint or seclusion, as well as those who have been in restraint or seclusion during their hospital stay (include both violent or self-destructive patients as well as non-violent, non-self-destructive patients).
3. What evidence is there that hospital staff identified the reason for the restraint or seclusion, and determined that other less restrictive measures would not be effective before applying the restraint?
4. Interview staff who work directly with patients to determine their understanding of the restraint and seclusion policies. If any patients are currently in restraint or seclusion, ascertain the rationale for use and when the patient was last monitored and assessed.
5. Is the actual use of restraints or seclusion consistent with hospital restraint and seclusion policies and procedures, as well as CMS requirements?
6. Review incident and accident reports to determine whether patient injuries occurred proximal to or during a restraint or seclusion intervention. Are incidents and

accidents occurring more frequently with restrained or secluded patients?

7. If record review indicates that restrained or secluded patients sustained injuries, determine what the hospital did to prevent additional injury. Determine if the hospital investigated possible changes to its restraint or seclusion policies.
8. Obtain data on the use of restraint and seclusion for a specified time period (e.g., 3 months) to determine any patterns in their use for specific units, shifts, days of the week, etc.
9. Does the number of patients who are restrained or secluded increase on weekends, on holidays, at night, on certain shifts; where contract nurses are used; in one unit more than other units? Such patterns of restraint or seclusion use may suggest that the intervention is not based on the patient's need, but on issues such as convenience, inadequate staffing or lack of staff training. Obtain nursing staffing schedules during time periods in question to determine if staffing levels impact the use of restraint or seclusion.
10. Interview a random sample of patients who were restrained to manage non-violent, non-self-destructive behavior. Were the reasons for the use of a restraint to manage non-violent, non-self-destructive behavior explained to the patient in understandable terms? Could the patient articulate his/her understanding?

NOTE: The instructions to surveyors regarding restraints to manage non-violent, non-self destructive behavior may be more applicable in a medical/surgical or skilled nursing setting than a mental health setting.

B. CALIFORNIA LAW

California law is virtually identical to federal law with respect to the rights of patients who are restrained or secluded. California law states that:

A patient has the right to be free from the use of seclusion and behavioral restraints of any form imposed as a means of coercion, discipline, convenience, or retaliation by staff. This right includes, but is not limited to, the right to be free from the use of a drug used in order to control behavior or to restrict the person's freedom of movement, if that drug is not a standard treatment for the person's medical or psychiatric condition.

[Health and Safety Code Section 1180.4(k); Title 9, California Code of Regulations, Section 865.4] (Although the last sentence in the state law is not included in the patients' rights portion of the federal law, it is included elsewhere in the federal law.) (See "Drug Used as a Restraint," page 5.6.)

III. GENERAL INFORMATION REGARDING RESTRAINT AND SECLUSION

A. QUICK SUMMARY OF RESTRAINT AND SECLUSION LAWS

If a hospital uses restraint or seclusion, the use must be:

1. In accordance with a physician's order and a written modification to the patient's plan of care;
2. Used in the least restrictive manner possible;
3. Used in accordance with safe and appropriate restraining techniques;
4. Selected only when other less restrictive measures have been found ineffective to protect the patient or others from harm; and
5. Ended at the earliest possible time.

The patient's attending physician must be consulted as soon as possible, if the attending physician did not order the restraint. In addition, the condition of the restrained or secluded patient must be continually assessed, monitored, and reevaluated. All staff involved in the care of restrained or secluded patients must have ongoing education and training in the proper and safe use of restraint and seclusion. A debriefing must follow each episode of restraint or seclusion.

Details of these requirements are discussed in this chapter.

B. TECHNIQUES

The use of restraint or seclusion must be implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with state law [42 C.F.R. Section 482.13(e)(4)(ii)]. State law does not contain specific requirements regarding restraint technique, except to describe certain prohibited techniques (see XV. "Prohibited Techniques," page 5.19.).

Title 22 regulations applicable to acute psychiatric hospitals require that restraints be easily removable in the event of fire or other emergency [Title 22, California Code of Regulations, Section 71545(d)]. In addition, if seclusion rooms are provided, they must be designed and equipped to ensure the safety of the patient [Title 22, California Code of Regulations, Section 71625].

The *Interpretive Guidelines* state that the use of restraint or seclusion must never act as a barrier to the provision of other interventions to meet the patients' needs.

SURVEY PROCEDURES

The *Interpretive Guidelines* direct surveyors to consider the following: