

- (12) Nutritional status.
- (13) Feeding tubes.
- (14) Dehydration/fluid maintenance.
- (15) Dental care.
- (16) Pressure ulcers.
- (17) Psychotropic drug use.
- (18) Physical restraints.

(g) *Criteria for CMS approval of alternate instrument.* To receive CMS approval, a State's alternate instrument must use the standardized format, organization, item labels and definitions, and instructions specified by CMS in the latest issuance of the State Operations Manual issued by CMS (CMS Pub. 7).

(h) *State MDS collection and data base requirements.* (1) As part of facility survey responsibilities, the State must establish and maintain an MDS Database, and must do the following:

- (i) Use a system to collect, store, and analyze data that is developed or approved by CMS.
- (ii) Obtain CMS approval before modifying any parts of the CMS standard system other than those listed in paragraph (h)(2) of this section (which may not be modified).
- (iii) Specify to a facility the method of transmission of data to the State, and instruct the facility on this method.
- (iv) Upon receipt of data from a facility, edit the data, as specified by CMS, and ensure that a facility resolves errors.
- (v) At least monthly, transmit to CMS all edited MDS records received during that period, according to formats specified by CMS, and correct and retransmit rejected data as needed.
- (vi) Analyze data and generate reports, as specified by CMS.

(2) The State may not modify any aspect of the standard system that pertains to the following:

- (i) Standard approvable RAI criteria specified in the State Operations Manual issued by CMS (CMS Pub. 7) (MDS item labels and definitions, RAPs and utilization guidelines).
- (ii) Standardized record formats and validation edits specified in the State Operations Manual issued by CMS (CMS Pub. 7).
- (iii) Standard facility encoding and transmission methods specified in the

State Operations Manual issued by CMS (CMS Pub. 7).

(i) *State identification of agency that collects RAI data.* The State must identify the component agency that collects RAI data, and ensure that this agency restricts access to the data except for the following:

(1) Reports that contain no resident-identifiable data.

(2) Transmission of data and reports to CMS.

(3) Transmission of data and reports to the State agency that conducts surveys to ensure compliance with Medicare and Medicaid participation requirements, for purposes related to this function.

(4) Transmission of data and reports to the State Medicaid agency for purposes directly related to the administration of the State Medicaid plan.

(5) Transmission of data and reports to other entities only when authorized as a routine use by CMS.

(j) *Resident-identifiable data.* (1) The State may not release information that is resident-identifiable to the public.

(2) The State may not release RAI data that is resident-identifiable except in accordance with a written agreement under which the recipient agrees to be bound by the restrictions described in paragraph (i) of this section.

[62 FR 67212, Dec. 23, 1997]

Subpart G—Condition of Participation for the Use of Restraint or Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services for Individuals Under Age 21

SOURCE: 66 FR 7161, Jan. 22, 2001, unless otherwise noted.

§ 483.350 Basis and scope.

(a) *Statutory basis.* Sections 1905(a)(16) and (h) of the Act provide that inpatient psychiatric services for individuals under age 21 include only inpatient services that are provided in an institution (or distinct part thereof) that is a psychiatric hospital as defined

in section 1861(f) of the Act or in another inpatient setting that the Secretary has specified in regulations. Additionally, the Children's Health Act of 2000 (Pub. L. 106-310) imposes procedural reporting and training requirements regarding the use of restraints and involuntary seclusion in facilities, specifically including facilities that provide inpatient psychiatric services for children under the age of 21 as defined by sections 1905(a)(16) and (h) of the Act.

(b) *Scope.* This subpart imposes requirements regarding the use of restraint or seclusion in psychiatric residential treatment facilities, that are not hospitals, providing inpatient psychiatric services to individuals under age 21.

§ 483.352 Definitions.

For purposes of this subpart, the following definitions apply:

Drug used as a restraint means any drug that—

- (1) Is administered to manage a resident's behavior in a way that reduces the safety risk to the resident or others;
- (2) Has the temporary effect of restricting the resident's freedom of movement; and
- (3) Is not a standard treatment for the resident's medical or psychiatric condition.

Emergency safety intervention means the use of restraint or seclusion as an immediate response to an emergency safety situation.

Emergency safety situation means unanticipated resident behavior that places the resident or others at serious threat of violence or injury if no intervention occurs and that calls for an emergency safety intervention as defined in this section.

Mechanical restraint means any device attached or adjacent to the resident's body that he or she cannot easily remove that restricts freedom of movement or normal access to his or her body.

Minor means a minor as defined under State law and, for the purpose of this subpart, includes a resident who has been declared legally incompetent by the applicable State court.

Personal restraint means the application of physical force without the use of any device, for the purposes of restraining the free movement of a resident's body. The term personal restraint does not include briefly holding without undue force a resident in order to calm or comfort him or her, or holding a resident's hand to safely escort a resident from one area to another.

Psychiatric Residential Treatment Facility means a facility other than a hospital, that provides psychiatric services, as described in subpart D of part 441 of this chapter, to individuals under age 21, in an inpatient setting.

Restraint means a "personal restraint," "mechanical restraint," or "drug used as a restraint" as defined in this section.

Seclusion means the involuntary confinement of a resident alone in a room or an area from which the resident is physically prevented from leaving.

Serious injury means any significant impairment of the physical condition of the resident as determined by qualified medical personnel. This includes, but is not limited to, burns, lacerations, bone fractures, substantial hematoma, and injuries to internal organs, whether self-inflicted or inflicted by someone else.

Staff means those individuals with responsibility for managing a resident's health or participating in an emergency safety intervention and who are employed by the facility on a full-time, part-time, or contract basis.

Time out means the restriction of a resident for a period of time to a designated area from which the resident is not physically prevented from leaving, for the purpose of providing the resident an opportunity to regain self-control.

[66 FR 7161, Jan. 22, 2001, as amended at 66 FR 28116, May 22, 2001]

§ 483.354 General requirements for psychiatric residential treatment facilities.

A psychiatric residential treatment facility must meet the requirements in § 441.151 through § 441.182 of this chapter.