

(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