



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-14-PRTF

DATE: December 19, 2014

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Guidance Related to New State Operating Manual and Appendix N for
Psychiatric Residential Treatment Facilities (PRTF)

Memorandum Summary

- ***Guidance Updated:*** The Centers for Medicare & Medicaid Services (CMS) has a new State Operating Manual and interpretive guidelines in the following State Operations Manual (SOM) Appendices to reflect recent amendments to the applicable Conditions of Participation (CoPs):
 - Appendix N – PRTF
- ***Effective Dates:*** The revised regulations and their associated guidance were effective July 11, 2014, with the exception of the RHC change concerning the requirement to employ at least one Nurse Practitioner (NP) or Physician’s Assistant (PA); this latter change was effective July 1, 2014.

An interim final rule establishing standards for the use of restraint and seclusion in PRTFs providing inpatient psychiatric services for individuals under age 21 (the Psych Under 21 rule) was published on January 22, 2001. This rule established a definition of a PRTF that is not a hospital and that may furnish covered inpatient psychiatric services for individuals under age 21. The rule also established a Condition of Participation (CoP) for the use of restraint and seclusion that PRTFs must meet in order to provide, or to continue to provide this Medicaid inpatient benefit. The CoP specifies requirements designed to protect the residents against the improper use of restraint and seclusion. This interim rule also established validation survey, complaint survey and reporting requirements as well as annual attestation requirements.

Since December 2004, State Survey Agencies (SA) has had no direction specific to PRTFs in the SOM and has used an interim final guidelines for PRTF survey procedures and interpretive guidelines (IG). The new SOM and new interim procedures, see attachments, have been revised and are now final in the SOM at Sections 2830-2834 and Appendix N.

Summary of Key Changes:

PRTF Condition of Participation, Part 483, subpart G

- State Operating Manual

A new SOM was created due to no existing PRTF program specific operating certification processes.

- Appendix N-Interpretive Guidelines

A final version of Appendix N- interpretive guidelines was created to provide guidance and protocol for surveyors.

An advance copy of the new SOM and Appendices N is attached. At a later date the on-line SOM will be revised, and may include further minor, non-substantive changes.

Questions concerning this chapter or memo may be addressed to Don Howard at donald.howard@cms.hhs.gov or Peter Ajuonuma at peter.ajuonuma@cms.hhs.gov .

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

Attachment – Advance copy of the new SOM and Appendices N.

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal

Date:

SUBJECT: Addition of Psychiatric Residential Treatment Facilities (PRTF) State Operating Manual (SOM) to Chapter 2.

I. SUMMARY OF CHANGES: Addition to Chapter 2 of the State Operations Manual, the Certification Process. Sections 2830-2834 detail the survey process for psychiatric residential treatment facilities.

NEW/REVISED MATERIAL - **EFFECTIVE DATE:** Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N	Chapter 2/Table of Contents
N	Chapter 2/Note: DOMA
N	Chapter 2/2830/PRTF-Citations and Definitions
N	Chapter 2/2830/2830A/Citations
N	Chapter 2/2830/2830B/ Definitions
N	Chapter 2/2831/Determination-Making Authority
N	Chapter 2/2831/2831A/Survey Agency and State Medicaid Agency Interaction
N	Chapter 2/2831/2831B/ Authorization of Certification Expenditures
N	Chapter 2/2831/2831C/Look-Behind Authority on State Determinations
N	Chapter 2/2831D/Appeals

N	Chapter 2/2831/2831D.1/ State Appeals
N	Chapter 2/2831/2831D.2/Facility Appeals
N	Chapter 2/2831/2831E/Accreditation
N	Chapter 2/2832/Survey Agency, State Medicaid Agency, and PRTF Responsibilities and Obligations
N	Chapter 2/2832/2832A/Attestations
N	Chapter 2/2832/2832B/Plan of Correction (POC)
N	Chapter 2/2832/2832C/Assigning CMS Certification Numbers (CCN)
N	Chapter 2/2832/2832D/ASPEN Data Input
N	Chapter 2/2832/2832E/Multi-State Issues and Interagency Relationships
N	Chapter 2/2832/2832E.1/State-to-State Differences
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N	Chapter 2/2833/2833C.2/On-Site Survey Procedures
N	Chapter 2/2833/2833C.2a/Entrance Conference
N	Chapter 2/2833/2833C.3/Survey Team Composition
N	Chapter 2/2833/2833C.4/Information Gathering
N	Chapter 2/2833/2833C.4a/ Task 1-Representative Sample of Residents- Selection Methodology

N	Chapter 2/2833/2833C.4b/Task 2-Record Review of Individuals in the Sample
N	Chapter 2/2833/2833C.4c/Task 3-Review of Other Records
N	Chapter 2/2833/2833C.4d/Task 4-Direct Resident Observations
N	Chapter 2/2833/2833C.4e/Task 5-Interviews
N	Chapter 2/2833/2833C.4f/Task 6-Visit To Each Area Of The Facility Serving Residents
N	Chapter 2/2833/2833C.4g/Task 7-Compliance Determination and Preparation for Exit Conference
N	Chapter 2/2834/Other Applicable SOM Sections

III. FUNDING: No additional funding will be provided by CMS; State activities are to be carried out within their FY 2015 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

State Operations Manual

Chapter 2 - The Certification Process

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2834 - Other Applicable SOM Sections

Psychiatric Residential Treatment Facilities (PRTFs)
(Rev.)

NOTE: Under the Defense of Marriage Act (DOMA): Every psychiatric hospital/facility is expected to recognize all state-sanctioned marriages and spouses for purposes of compliance with the Conditions of Participation and regulatory requirements, regardless of any laws to the contrary of the state or locality where the hospital/facility is located. In the regulation or this guidance, and in every instance where the following terms appear:

- **“spouse”** means an individual who is married to another individual as a result of a state-sanctioned marriage, including a same-sex marriage, regardless of whether the state where the facility is located permits such marriages to occur;
- **“marriage”** means a state-sanctioned marriage, including a same-sex marriage, regardless of whether the state where the facility is located permits such marriages to occur;
- **“family”** includes, but is not limited to, an individual’s “spouse” (see above); and
- **“relative,”** when used as a noun, includes but is not limited to, an individual’s “spouse” (see above).

Furthermore, wherever the text of a regulation or associated guidance includes a reference to a patient’s “representative,” “surrogate,” “support person,” “next-of-kin,” or similar term in such a manner as would normally implicitly or explicitly include a spousal relationship, the terms are to be interpreted as indicated above.

2830 – PRTF – Citations and Description

2830A – Citations

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. (42 CFR 483.350(a)).

Condition of Participation (CoP). The Condition of Participation for PRTFs is contained in 42 CFR Part 483, Subpart G: Condition of Participation for the Use of Restraint or Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services for Individuals Under 21. **Appendix N** of this manual contains the Interpretive Guidelines for surveyors.

2830B – Definitions

A Psychiatric Residential Treatment Facility (PRTF) is defined as 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. Sections 441.151, in subpart D of 42 CFR indicates that PRTFs must be accredited by the Joint Commission, the Commission on Accreditation of Rehabilitation Facilities (CARF), the Council on Accreditation of Services for Families and Children (COA), or by any other accrediting organization with comparable standards that is recognized by the State. PRTFs, as indicated in § 483.374 must also have either a current provider agreement with the State Medicaid agency or if enrolling as a Medicaid provider must execute a provider agreement with the State Medicaid agency.

Inpatient Psychiatric Services for Individuals Under age 21 Benefit. – Inpatient psychiatric services for individuals under 21 is a Medicaid benefit as provided by section 1905(a)(16) of the Social Security Act, the provision of these services is an optional benefit for individual states. Although a state may choose to or not to offer PRTF services in its state plan, the benefit must be provided in all States to those individuals who are determined during the course of an Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) screen to need this type of inpatient psychiatric care. Under the EPSDT provisions at section 1905(r)(5) of the Act, States must provide any service listed in section 1905(a) of the Act that is needed to correct or ameliorate defects and physical and mental conditions discovered by EPSDT screening services, whether or not the service is covered under the State plan.

Condition of Participation for the Use of Restraint and Seclusion. – PRTFs must comply with the requirements of 42 CFR 483.350, subpart G in order to participate in the Medicaid program. The interpretive guidelines for the Condition of Participation may be found in Appendix N and include discussion of the following eleven standards of the Condition:

- *General requirements for psychiatric residential treatment;*
- *Resident protections;*
- *Orders for the use of restraint or seclusion;*
- *Consultation with treatment team physician;*
- *Monitoring of residents in and/or immediately following restraint or seclusion;*
- *Requirements for notifying parents or legal guardians;*
- *Application of time out;*
- *Post-intervention debriefing;*
- *Medical treatment for injuries resulting from an emergency safety intervention;*
- *Facility reporting requirements;*
- *Facility’s responsibility in educating and training its staff.*

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.

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

Minor means a minor as defined under State law and, for the purpose of this as defined in §483.352, includes a resident who has been declared legally incompetent by the applicable State court.

Resident means an individual under age 21(as described in subpart D of §441.151) receiving psychiatric treatment in a PRTF.

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 physical condition of 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 individuals who participate in caring for the resident, who have the responsibility for managing a resident's treatment 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.

Drug used as a restraint means any medication that is administered to manage a resident's behavior, which may have temporary effect of restricting the resident's freedom of movement; and is not a standard or routine treatment for the resident's medical or psychiatric condition.

2831 – Determination-Making Authority

2831A – Survey Agency and State Medicaid Agency Interaction

Section 1902(a)(33) of the Act requires that the same State survey agency (SA) that certifies Medicare provider and supplier eligibility also make the determination of eligibility to participate in Medicaid. The law also requires that there be a separately designated single SA responsible for the overall management of the Medicaid program (42 CFR 431.610(b)). Therefore, in each State, a State Medicaid Agency (SMA) is ultimately responsible for Medicaid program administration. Each SMA enters into an interagency agreement with its certifying SA establishing the determination-making

function of the SA and providing for the application of Federal certification standards and procedures.

In addition, 42 CFR 431.610(e) and (f) require that the Medicaid State plan must designate the agency that is responsible to ensure that institutions and agencies meet the requirements for participation in the Medicaid program. The SMA must accept the SA's certification decisions as final, but exercise its own determination whether to enter into an agreement with psychiatric residential treatment facilities (PRTFs), while if the SA determines the PRTF is out of compliance, the SMA may not enter into an agreement. The SMA is responsible for reviewing certifications to ensure that the SA adhered to procedural requirements. If the SMA disagrees with the SA's certification, the SMA should first contact the SA to resolve the issue. If the issue is not resolved after contact with the SA, the SMA should present the issue to the applicable CMS-Regional Office (RO). (See discussion in State Medicaid Manual (SMM) §2084.3A).

2831B – Authorization of Certification Expenditures

Authority to approve Medicare certification budgets and expenditures is delegated to the designated CMS Consortium or Regional Administrator(s). Authority to approve or disapprove Federal Financial Participation (FFP) in Medicaid certification expenses is delegated to the CMS Associate Regional Administrators or the Consortium Survey and Certification Officer where an Associate Regional Administrator is not present.

2831C – Look-Behind Authority on State Determinations

The Secretary has authority under §§1902(a)(33), 1919(g)(3), and 1910(b)(1) of the Act cancel approval of all Medicaid facilities that do not meet Federal health or safety requirements. Such a determination is in lieu of, or overrides a determination by the State and is binding on the SMA. Section 1902(a)(33) of the Act gives CMS the authority to question State determinations regarding Medicaid facilities' compliance with Federal requirements and authorizes CMS to make independent and binding determinations concerning the extent to which individual institutions and agencies meet requirements for participation. CMS has the authority to “look behind” State determinations and, with cause, to make binding determinations. This authority allows CMS to validate State determinations concerning the extent to which individual institutions and agencies meet the requirements for participation (Section 1902 (a)(33)(B) of the Act).

This look-behind authority accords CMS the ability to cancel the approval of a facility to participate in the Medicaid program when CMS determines the facility fails to comply substantially with the Conditions of Participation. (See Section 1902 (a)(33)(B) and SMM §2084.3). Also refer to 42 CFR Part 483, Subpart G for PRTF Conditions of Participation.

Another part of CMS's look- behind authority provides that a provider agreement is considered by CMS to be invalid for purposes of providing FFP to the State if the State failed to adhere to federal procedures. For example, the SMA may have issued the

provider agreement even though the SA determined that the facility was not in compliance with the COP. In that case, the agreement is void from its inception. This authority is established by Section 1902 (a)(33)(B) of the Act. (See discussion of look behind authority in SMM §2084.3 and SOM §3042).

2831D – Appeals

2831D.1- State Appeals

A State has the right to appeal the Administrator’s decision to withhold federal funds for Medicaid programs due to failure to comply with the Federal regulations; as stated in 42 CFR Part 430 Subpart D “(a) This subpart sets forth the rules for hearings to States that appeal a decision to disapprove State plan material (under §430.18) or to withhold Federal funds (under §430.35), because the State plan or State practice in the Medicaid program is not in compliance with Federal requirements. (b) Nothing in this subpart is intended to preclude or limit negotiations between CMS and the State, whether before, during, or after the hearing to resolve the issues that are, or otherwise would be, considered at the hearing. Such negotiations and resolution of issues are not part of the hearing, and are not governed by the rules in this subpart except as expressly provided.”

2831D.2 – Facility Appeals

If a Medicaid-only facility requests a hearing, such hearing must be completed either before or within 120 days after the effective date of the adverse action. (See SMM §2040.) Detailed Medicaid appeal procedures are provided by the State. In the case of “look-behind” terminations, CMS notifies the facility of the termination and whether it has a right to request a hearing before a Federal Administrative Law Judge. Although a facility can appeal a look-behind determination that found the facility out of compliance with the conditions of participation, the facility has no right to request for an appeal in cases where CMS disallowed FFP on the grounds of an SA’s improper or inappropriate certification of the facility. (See SMM §2084.3E).

2831E – Accreditation

Federal regulations at 42 CFR 441.151(2)(ii) require that PRTFs are to be accredited by the Joint Commission, the COA, the CARF or by any other accrediting organization with comparable standards that is recognized by the State.

2832 – Survey Agency, State Medicaid Agency, and PRTF Responsibilities & Obligations

2832A – Attestations

State Responsibilities – The SA of the State which is surveying the PRTF inputs the initial attestation information into ASPEN, and continually thereafter.

- ***PRTF Responsibilities** – PRTFs must submit attestation statements to each SMA where they have established a provider agreement.*
- *Attestation statements are to be submitted annually and are due on July 21st of each fiscal year. However, if July 21st occurs on a weekend or holiday, the attestation is due on the first business day following the weekend or holiday.*
- *Attestations must include the following information:*
 - *Facility General Characteristics: name, address, telephone number of the facility, and a State provider identification number;*
 - *Facility Specific Characteristics:*
 - + *Bed size;*
 - + *Number of individuals currently served within the PRTF who are provided service based on their eligibility for the Medicaid Inpatient Psychiatric Services for Individuals Under age 21 Benefit (Psych under 21);*
 - + *Number of individuals, if any, whose Medicaid Inpatient Psychiatric Services Under 21 Benefit is paid for by any State other than the State of the PRTF identified in this attestation letter; and*
 - + *List all States from which the PRTF has ever received Medicaid payment for the provision of Psych under 21 services.*
 - *The signature of the facility director;*
 - *The date the attestation was signed;*
 - *A statement certifying that the facility currently meets all of the requirements of Part 483, Subpart G governing the use of restraint and seclusion;*
 - *A statement acknowledging the right of the SA (or its agents) and, if necessary, CMS to conduct an on site survey at any time to validate the facility’s compliance with the requirements of the rule, to investigate complaints lodged against the facility, or to investigate serious occurrences;*
 - *A statement that the facility will submit a new attestation of compliance annually and in the event a new facility director is appointed.*

2832B – Plan of Correction (POC)

Regulations at 42 CFR 488.28(a) allow recertification of providers with deficiencies at the Standard or Condition level “only if the facility has submitted an acceptable Plan of Correction (POC) for achieving compliance within a reasonable period of time acceptable to the Secretary.” Failure to submit a POC may result in termination of the provider agreement as authorized by §489.53(a)(1). After a POC is submitted, the certifying SMA, or in some cases the CMS Regional Office, makes the determination of the appropriateness of the POC for it to be acceptable.

2832C – Assigning CMS Certification Numbers (CCN)

A CCN code is assigned based on where the PRTF is physically located. Processing of requests for payment is usually keyed to the Federal identification number; however this

identification number is for Online Survey, Certification, and Reporting System (OSCAR) tracking purposes only.

The certification numbers for PRTFs will have five digits and one letter. The first two digits identify the State in which the PRTF facility is located. This number is then followed by the letter L and is then followed by three digits and is numbered according to the order in which a facility was identified as a PRTF in their State. All State codes are listed in SOM §2779. For example, a PRTF located in Maryland would have a State code of “21.” This would then be followed by the letter “L” and identified with a three digit number. For example, if it was the fourth PRTF identified by the State, the PRTF’s CCN would be 21L004. (See SOM §2779B)

2832D – ASPEN Data Input

- *The surveying SA has the responsibility of entering the survey data into ASPEN. After the CCN is assigned to the PRTF, the SA is to enter information received from the PRTF annual attestation as well as information from recertification or complaint surveys. It is also the responsibility of the SA to update the information as needed. The SA is to input information from Forms CMS- 1539, CMS- 670, CMS-2567 and if applicable, CMS-2567B.*
- *The initial input of information from attestation must be done by the SA of the State surveying the PRTF, even if the State in which the PRTF is located does not include the Inpatient Psychiatric Services for Individuals Under 21 Benefit in its State plan.*
- *Maintaining attestation and survey information is the responsibility of the SA conducting complaint and validation surveys.*

2832E – Multi-State Issues & Interagency Relationships

2832E.1 – State-to-State Differences

There are several State-to-State differences in the provision of services for individuals who qualify for the Inpatient Psychiatric Services for Individuals Under 21 Benefit. The following factors determine where an individual receives services and who has surveying responsibilities.

1. *States may or may not have the Inpatient Psychiatric Services for Individuals Under 21 benefit in their State plan.*
2. *States may or may not have a PRTF within its borders.*
3. *States have an obligation to provide inpatient psychiatric services for individuals under 21 years of age regardless of whether or not the benefit is in their State plan or a PRTF is within its borders.*

A State will either have the Inpatient Psychiatric Services for Individuals Under 21 Benefit in its State Plan or it will not. However, not all States will have a PRTF within its

borders that can meet the needs of its Medicaid beneficiaries and thus will have to transfer beneficiaries to another State to receive the needed service.

Occasionally, a SMA may elect to send a patient out of State to receive the Psych Under 21 Benefit, (reference S&C Memo of July 3, 2013: 13-45-PRTF). It is the responsibility of the transferring SMA to ensure that these services are provided in a certified PRTF. In some instances, the facility selected (i.e., receiving facility) is located in a State that does not include PRTF services in its Medicaid State Plan and thus no facilities in that State are certified as PRTFs. If the transferring SMA still wishes to transfer the patient to such a facility, it must make a written agreement for the certification of that facility prior to the patient's transfer.

The initial certification of a PRTF is currently accomplished through an attestation process. The SA, through an agreement with the SMA, conducts surveys (Recertification, Complaint Investigation, and Validation) at least every five (5) years to ensure that the facility remains in compliance with the applicable regulations and the assertions of the attestation. The SA makes a recommendation to the SMA for re-certification or termination. The SMA enters into a written agreement with the PRTF.

If the certifying SMA of one State wishes to have a facility in another State certified as a PRTF, there are three options available for the SMA regarding the survey portion of the certification process:

- The SMA may make a written agreement with the SA of the State in which the facility is located to conduct the surveys of the facility;*
- The SMA may make a written agreement with the SA located within their own State to travel to the receiving State to conduct the surveys; or*
- The SMA may make a written agreement with any other SA to conduct the surveys of the facility.*

SAs in States where the Medicaid State Plan does not include PRTF services may not have trained personnel or may not have the available resources to conduct these PRTF surveys since this is not a routine part of their workload. If the SMA of one State wishes to certify a PRTF in another State and approaches the other State's SA to conduct the survey activity, the other SA may agree if they feel they have the necessary resources or may decline if they feel they do not. They are under no obligation to perform the work for the SMA of another State.

If the SA from the State where the facility is located is not able to perform the survey activity, the SMA seeking survey of the PRTF may enter into a written agreement with any other State SA (including the SA located within in SMA's own State) that has the resources and appropriately trained personnel. The SA that conducts the surveys would then be responsible for inputting the survey information into ASPEN. The SMA requesting the survey will ensure that the survey information is entered into ASPEN and ensure that re-certification surveys are conducted at least once every five (5) years. The SMA requesting the survey has the authority to enforce non-compliance actions.

2832E.2 – Action for Non-Compliance and Termination

The SMA may take termination action against the PRTF if the SA determines the PRTF is not in compliance with the regulation or fails to appropriately report a death incident. If there are conflicting determinations between the SA and the SMA or there are conflicts that arise based on multi-state issues, then the applicable RO must be informed of the decisions. The RO will settle these conflicts before adverse findings are placed into ASPEN. In the case of multi-state issues, if the SA and the SMA are located in two different Regions, the applicable RO is defined as the RO for the state in which the SMA is located. The facility must submit their plan of correction to the SA of the State that conducted the survey.

If the survey findings do not rise to the condition level, but are only standard level deficiencies, it is still the responsibility of the surveying State to send their findings to the certifying SMA and the applicable Regional Office (RO). It is the responsibility of the certifying SMA to review and accept the facility's plan of correction.

2832E.3 – State Agency – Who Can Survey

The SMA identifies which agency is responsible for conducting survey and certification oversight for its PRTFs. Federal regulation requires that the Medicaid “State plan must designate, as the State authority responsible for establishing and maintaining health standards for private or public institutions that provide services to Medicaid beneficiaries, the same State agency that is used by the Secretary to determine qualifications of institutions and suppliers of services to participate in Medicare.” (Emphasis added). (See 42 CFR 431.610(b)).

During surveys to determine compliance with the PRTF condition of participation, if findings show that the condition of participation for the PRTF is not met it is the responsibility of the SMA of the State that certified the PRTF to consider termination of the provider agreement. If findings do not rise to the condition level, but are standard level deficiencies, it is still the responsibility of the surveying State to send their findings to the SMA and the applicable RO. Facilities where standard level deficiencies have been found are required to submit a plan of correction to the surveying SA.

2833 – Survey Process

2833A – Survey Types

2833A.1 – Recertification Surveys

SAs are required to validate the attestation statements for a 20 percent of all PRTFs in their state on an annual basis. Validation requires that the SA review attestation letters, conduct on-site review of PRTFs based on criteria established in 42 CFR 441.151

through 441.156, and determine compliance with federal standards and regulations, as set forth in 42 CFR 483, Subpart G and further discussed in the interpretive guidelines.

2833A.2 – Complaint Surveys

1. Immediate Jeopardy

The SA conducts an investigation of all allegations which may represent an immediate jeopardy situation within 2 working days of complaint receipt.

“Immediate Jeopardy,” as defined in 42 CFR 489.3, is a situation in which the provider’s noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident. “Serious injury” is defined as any significant impairment of the physical condition of the resident as determined by qualified medical personnel. The term “serious injury” can be equated with “abuse or neglect.” Appendix Q lists abuse and neglect as a trigger to call an immediate jeopardy. Refer to appendix Q for complete guidance on immediate jeopardy. To determine if an immediate jeopardy situation is present and ongoing, an assessment of each complaint intake must be made.

Exception – If the SA receives a restraint/seclusion death report, the SA should complete the investigation of this report within 5 working days of receipt of survey authorization from the RO. This investigation involves both on-site and off-site review. The ACTS report should be reviewed to determine facility history.

2. Non-immediate jeopardy

For non-immediate jeopardy situations, the SMA in conjunction with the SA will establish a mechanism by which to prioritize the nature of complaints. The SA should assess facility compliance with the established standards and regulations as provided in 42 CFR part 483 subpart G, (§§ 483.350 through 483.376) with additional guidance at §§ 441.150 through 441.156. If a complaint is received by CMS, CMS will notify the appropriate SA, who will then notify the SMA about the complaint, any ongoing investigation, findings, or decision regarding the complaint.

The SMA must report all serious occurrences, as defined in 42 CFR 483.374(b), to its SA and the SA must conduct both recertification and complaint surveys based on regulations established by the 42 CFR 483 subpart G and further discussed within the interpretive guidelines as established in Appendix N. The SA will be advised annually in the CMS Mission and Priority Document (MPD) on the expected validation requirements for its State’s psychiatric residential treatment facilities.

2833B – Survey Frequency

1. Frequency – The SAs are required to conduct recertification surveys for 20 percent of all PRTFs in the state each year and for all PRTFs within a State within a 5-year period. Complaint surveys do not count towards a State’s 20 percent required recertification surveys.

2833C – Survey Procedures

Pre-survey procedures, onsite survey procedures, required CMS forms, and the interpretive guidelines are located in Appendix N.

2833C 1 PRE-SURVEY PROCEDURES

Under CMS policy, surveys for all providers and suppliers must be unannounced. While the unannounced surveys may sometimes result in some minor difficulties, this policy and practice represents public attitudes and expectations toward effective compliance with the regulation and survey standards. If there is any conflict with internal State policies and practices, the State survey agency (SA) should discuss the problem with its State Medicaid Agency (SMA).

2833C.2 ON-SITE SURVEY PROCEDURES

2833C.2a ENTRANCE CONFERENCE

The entrance conference sets the tone for the entire survey. The surveyor should be well prepared, courteous, and make requests, not demands. Upon arrival, the surveyor does the following:

- *Presents the appropriate identification;*
- *Introduces other team members who must also furnish appropriate identification;*
- *Informs the facility's administrator, director, or supervisor of the purpose of the Survey;*
- *Provides expected duration and time schedule of the survey; and*
- *Provides the facility with an overview of the survey and explains the process.*

During the entrance conference, the surveyors should:

- A. *Request a listing of all residents at the facility, including their age or date of birth, and who in the past 12 months:*
 - *Have been secluded or restrained;*
 - *Have been placed in time out;*
 - *Received medication for behavior management;*
 - *Have been injured or hospitalized as a result of restraint or seclusion intervention;*
 - *Had a serious occurrence that was reported regardless of whether it is related to a safety intervention. A Serious occurrence as defined in the regulations is a resident's death, serious injury to a resident, or a resident's suicide attempt;*
 - *Was transferred to a hospital for acute care services; and*
 - *Died while in the facility.*

- B. *Inform the facility that the survey process will include:*
 - *A physical onsite tour of the facility;*

- *Direct observations, and interviews with residents, families/guardians, and personnel involved in the residents' care, (ask that appropriate family and guardians be made aware of potential interviews); and*
 - *Review of relevant program, treatments, and residents records.*
- C. Establish personnel availability and discuss approximate time frames for survey completion.*
- D. Provide approximate or expected exit date and time.*
- E. Ask if there are any locked areas which require a key for entry, and if there are locked areas, how would the surveyor be able to access those areas.*
- F. Ask the facility to identify which staff will be available for questions/assistance.*
- G. Provide a list and category of the facility staff the surveyor will need to interview during the course of the survey.*

2833C.3. Survey Team Composition

Survey team size and composition will vary according to the size of the facility and the purpose of the survey. Professional disciplines and experience represented on the survey team should reflect the expertise needed to determine compliance with the CoP. All survey team members must meet education and training qualifications as specified in the SOM §4009 and must have successfully completed the CMS Basic PRTF survey training course.

Any SA or federal surveyor who serves on the PRTF survey team must have completed the PRTF basic survey training course successfully.

2833C.4- INFORMATION GATHERING

2833C.4a TASK 1 - REPRESENTATIVE SAMPLE OF RESIDENTS - SELECTION METHODOLOGY

Purpose of the Sample - The purpose of drawing a sample of residents from the facility is to ensure all the regulatory requirements is applied to a proportionate representation of all residents. The sampling methodology outlined below is not intended to create a "statistically valid" sample. The methodology allows for flexibility in sample selection based on the surveyor's observations while on-site at the facility.

The surveyor must conduct interviews and observations of the sampled residents within the context of the environment in which the resident lives, receives treatment and spends leisure time. Although focus should be on the sampled residents, the behavior and interactions of all other residents and staff within the environment also contributes to the total context.

After the resident sample is collected, additional information about the facility's practices, as well as additional resident information may emerge. Surveyors may add residents to the sample based on observations or incidents that occur during the survey. The reason for adding residents to the sample must be documented. Surveyors must add any resident who is restrained or secluded during the survey to the sample. A resident substitution may be made in the sample only if it is determined that including such a resident in the sample would negatively impact his/her treatment. For example, when interviewing/observing a resident with diagnosis of paranoid schizophrenia, may result in acute exacerbation of psychiatric symptoms. When a substitution is made within the sample, surveyors must ensure that the resident added to the sample meets the same requirements, and is selected from the same age group as the resident he/she is replacing.

Sample Considerations–

- Survey team should not allow the facility to select the resident sample.*
- Sample selection should be completed before beginning review of residents or other survey activities.*
- Survey team must randomly select sample from the list of all the residents provided by the facility.*
- The sample should represent various age groups of the facility residents. The three main age groups are: ages 18 to 21; 9 to 17 and under 9 years.*
- The sample should include residents who experienced restraint, seclusion or time-out in the past 12 month (if any); these residents should make up at least 50% of total sample.*

Sample Selection:

Follow the guidance below using the appropriate ratio to select and calculate the size of the sample.

Census:

*4-8 residents
9-16 residents
17-50 residents
51 or more residents*

Sample Ratio:

*4 residents
6 residents
8 residents
10 residents*

Please note:

- Due to unique characteristics the PRTF population and the seriousness of the Condition of Participation, surveyors should investigate further when a facility reports they have no current residents who have experienced either an ESI or time out procedure.*

To maximize the advantage of an interdisciplinary survey team, the survey team leader assigns each member an equitable number of individuals on whom to focus. Each

member of the team shares salient data about findings relative to his or her assigned individuals. Consult with one another, on a regular basis during the survey, to maximize sharing of data, knowledge and competencies.

Documentation – Document the sample on form CMS-807 Surveyor Notes Worksheet - The team leader must ensure that information related to the sample is well documented and includes the following:

- 1. Summary listing of all resident information comprising the survey sample (including any additions or substitutions to the sample). At a minimum, identify:*
 - The record number of each resident chosen to be part of the sample;*
 - Any resident-identifier codes used as a reference to protect the resident's confidentiality; and*
 - The record number of each death record reviewed.*

- 2. Description of the representative sample selection must include:*
 - The number of residents in the sample;*
 - The distribution of the individuals in the sample;*
 - The number, if any, of the residents added to the sample, including the reason added, e.g., complaint investigation; and*
 - The number, if any, of the residents substituted in the sample, including the reason for withdrawing the original resident record.*

2833C.4b TASK 2 - RECORD REVIEW OF INDIVIDUALS IN THE SAMPLE

Review each resident's record to determine appropriate compliance with the condition of participation (CoP) for the use of restraint or seclusion, and the regulation requirements in 42 CFR §§ 441.151 through 441.182. The primary purpose of the record review is to determine if the facility is complying with the requirements of:

- 1) Certification of need for services;*
- 2) Individual plan of care (treatment plan);*
- 3) Documentation of emergency situation and all events surrounding it;*
- 4) Management and outcome of emergency safety intervention; and*
- 5) Health and wellness of the residents.*

During record review, surveyors should be alert to instances of intramuscular medication use, safety hold and escort procedures, and any other procedures that could be mislabeled as not being restraints or seclusion. Utilize direct observations, resident interviews and record review to make informed compliance decisions. Ensure that the facility's definitions and perception of seclusion and restraint is in consonance with the definition that is contained in the regulation.

While reviewing the records, pay attention to key requirements such as: compliance with treatment team members' credentials, facility/program accreditation, and trends that may suggest that seclusion and restraint intervention are being overused or misused. Also look for records of accidents and incidents which may suggest resident's abuse,

neglect, bullying or vulnerability to injury. If there is any evidence of physical, verbal, emotional, or sexual abuse; surveyors must follow-up on the status and if required, implement the immediate jeopardy procedure as directed by Chapter 5 and Appendix Q of the SOM.

2833C.4c TASK 3- REVIEW OF OTHER RECORDS

A. Death Records - Review a list of all resident deaths, in the past 12 months. All team members must participate in the record review of residents who have died while at the facility. For death records, refer to form CMS-726, CMS Death Record Review Data Sheet. Evidence should exist of documented contact with appropriate Federal, State and local agencies notifying of the circumstances and demographics surrounding the resident's death and resulting outcomes from investigation by the PRTF and/or any of the appropriate Federal, State or local agencies.

B. Complaint Investigations - If a complaint is being investigated at the time of the survey, include the record(s) of the resident(s) of the complaint as part of the record review. If the resident named in the complaint is still in the facility, add him/her to the sample.

C. Policy and Procedures – Review the facility's policy and procedure documents on restraint, seclusion, and time out interventions. The policy must contain information about management of emergency safety intervention (ESI), and the facility's procedures regarding all the requirements of the CoP.

D. Serious Injury and Occurrence Report– Review all PRTF's serious injury and occurrence reports for at least past twelve months prior to the date of the present survey. Some individual state laws may preclude the facility from sharing detailed records of the incident. In such case, provide PRTFs an option as to whether or not they share these actual reports. In these States, surveyors should request a written summary of these reports. The PRTFs should provide this summary, as well as a copy of or citation to the applicable state law, within one working day of the entrance conference.

2833C.4d TASK 4 - DIRECT RESIDENT OBSERVATIONS

The purpose of direct observation is to determine the existence of effective therapeutic relationship between the facility staff and the residents. Staff must respect the rights of the residents and interact with them in a mutually productive manner. Direct observation also helps to determine how effective staff manages the milieu and efficiency of the application of de-escalation and other behavior management techniques. De-escalation techniques include: limit setting, therapeutic communication, redirection, conflict resolution, active listening techniques, and visualization.

Observe each sampled resident in as many treatment settings (therapy groups, activities, treatment team meetings, other types of meetings, and milieu interactions in the resident's environment) as possible. Visit as many treatment areas as time permits, and observe residents' activities during different time periods, including day and evening hours, if

possible; for team member's convenience or preference. Surveyors must never request the facility to alter a resident's schedule so that the surveyor will not have to work at other than their regular work times in order to observe the resident during the survey. The observation should be conducted for an amount of time sufficient to assess the sampled resident's responses and behaviors as well as staff responses to resident behaviors.

Documentation - If during resident observation the process of documentation will disrupt the activity in progress, the best option is to document after the observation is completed. Form CMS-3070I is an optional form but can be used to record observations if the surveyor so chooses. After observations are completed, compare observation result with the program/individual treatment plan for consistency.

Record the following information for each observation:

- Date and location;*
- Beginning and ending times of observation;*
- Number of residents present;*
- Approximate number of staff present*
- What the resident is doing (regardless of whether or not a scheduled therapeutic modality was in progress);*
- What the staff is doing;*
- The presence of disruptive behavior, and staff's intervention, if any; and,*
- Any other pertinent information.*

2833C.4e TASK 5 INTERVIEWS

Resident Interviews

Surveyors must interview all sample residents individually. However, an interview may not be conducted with a resident when it is determined by one of the individual plan of care team members, as described in §441.156(c), as being inappropriate for the resident's condition. Staff information and medical record documentation should support the rationale for not interviewing the resident.

When interviewing residents of a PRTF a surveyor should take into consideration the resident's age and psychiatric condition. Interviews with residents consist of questions directed at determining the resident's understanding of the treatment services indicated in their individual care plan and progress towards goals, type and quality of relationship with program staff, and their restraint or seclusion episode. In addition, the resident should be asked to what degree they felt safe while restrained or secluded and if they feel as if staff are working with them to prevent future restraint or seclusion usage.

Also ascertain if the resident felt that the restraint or seclusion was warranted based on their behavior. Interviewing should not take place in the direct presence of staff. However, a resident should be given an opportunity to have a staff member be within visual proximity if the resident so chooses. When an interview is deemed inappropriate

by the facility staff, the survey activities for review of that resident will consist of observations, staff interviews, and record reviews. Resident confidentiality must be respected, but if the surveyor does find a life-threatening situation, that information is shared with the staff. Listed below are suggested processes and questions that a surveyor may use during an interview.

Interview Setting:

Surveyors must respect resident's rights and ensure the setting of the interview is conducive and less restrictive. The surveyor should:

- 1. Request permission of the resident to talk with him/her individually.*
- 2. Provide the resident with information, such as surveyor name and purpose of the survey.*
- 3. Ensure resident privacy by conducting the interview in an appropriate location (low stimulus, on or off unit depending on resident restrictions, staff visible for surveyor and resident protection, if necessary). Staff should be easily available and may be present in the room, but should not be able to overhear conversation unless the resident makes a request for staff close physical presence.*

Suggested Interview Questions:

- Can you tell me why you are in this facility?*
- Tell me about your treatment goals?*
- Do you think you are making progress towards your treatment? Can you tell me the names of your medications and why you are taking them?*
- Do you have the opportunity to talk to members of your treatment team on a regular basis and how responsive are they to your interaction?*
- Can you describe to me your experience with the last time you were restrained/ secluded/ in timeout?*
- Where was staff located during your restraint/seclusion/ time out?*
- Has the treatment team discussed the incident with you? Did you and the team agree on a plan to reduce the frequency of these incidents? Please describe the plan to me.*
- Describe to me what incident that led to the restraint/seclusion/time out?*

Age Appropriate Adjustments – Surveyors should keep in mind varying age range of residents in the PRTF (toddlers to adolescents or young adults) and adjust their interview approach accordingly for a better result. For example, there are times when kneeling or sitting in a chair may be less intimidating to residents, and more appropriate to begin a conversation. Also the way a question is framed may determine how much information one can elicit, for instance, instead of asking: “Can you tell me why you are in this facility?” The question can be reworded into different series of probing questions to get at a better answer. For example, “Do you like living here?” “Do you know why you are living here?” “Can you tell me about living here?” It is important to note that different facilities and residents may perceive or interpret restraint/seclusion intervention based on their own understanding and frame of reference.

Staff Interviews

Because milieu interaction and therapeutic intervention involve both the staff and the residents, it is also important to interview the staff in order to ascertain their level of knowledge and understanding of the facility's restraint and seclusion policies and procedures. In order to ensure improved safety, staff must be adequately educated and oriented to their work environment. Staff should also be familiar with resident treatment plans and understand their role in facilitating the residents' attainment of the target treatment goals. Assess for consistent treatment approaches and collaboration among the interdisciplinary treatment team, as well as the outcomes experienced by the residents. Interview the following:

- *Treatment team member who has assigned treatment responsibility for each sample resident (case manager, primary therapist, resident care coordinator, advocate); and*
- *Other staff members who are involved with the resident, either through multidisciplinary treatment assignment (social worker, dance therapist, dietician) or through work assignment (professional and paraprofessional staff members assigned to resident's unit).*

During staff interviews, asking the following questions may help to elicit improved cooperation and more information:

- *Do you participate in the interdisciplinary treatment team; if yes, what role do you play?*
- *Did you contribute to treatment plan objectives/goals for sample residents and updates?*
- *How often is each resident's treatment plan reviewed?*
- *Can you describe the discharge plans for sample residents?*
- *Give examples of de-escalation techniques you were taught and how you utilize them when dealing with residents?*
- *How do you integrate treatment plan goals and objectives that have been developed as a result of seclusion or restraint episodes?*
- *How do you manage resident's emergency safety situation, and how you determine when to utilize a restraint or seclusion intervention?*
- *Describe to me, how staff implement, manage, and discontinue time out, restraint or seclusion.*
- *What behavior typically warrants interventions such as restraint or seclusion?*
- *Do you feel you are adequately prepared (through education and training) to handle behavioral safety situations and emergencies related to residents' care?*

Interviews with Parents and Legal Guardians

Surveyors will make a request to facility/program staff after the entrance conference to give sample residents family/guardian notice of a potential for interview. The interviews with parents and legal guardians should be conducted in addition to interviews with sampled residents. Interviews with parents and legal guardians should be conducted at their convenience with an opportunity for face-to-face interviews when feasible. In cases

where parents or legal guardians reside in another state or are unable or unwilling to meet face-to-face, telephone interviews should be conducted. Suggested questions:

- *Were you involved in formulation of your family member's treatment plan and discharge plans?*
- *Are you aware of the psychiatric medications your family member is taking and/or being prescribed while in treatment?*
- *Have you been able to communicate with members of your family member's treatment team?*
- *Do you know your family members treatment diagnosis, and do you understand what it means?*
- *Were you informed of the facility's policy on restraint and seclusion?*
- *Was the information presented in a manner that you could understand?*
- *Did you receive the information regarding the State Protection and Advocacy organization? What type of information should be reported to them?*
- *Were you contacted after a restraint or seclusion intervention?*
- *Were you given an opportunity to participate in the debriefing following restraint/seclusion use?*

Interviews with Department Heads and/or Facility Administrator

Conduct these interviews near the end of the survey if it is determined that questions were unanswerable by facility staff and interviewing directors or other facility leaders would prove useful to the survey process and the gathering of information. Base the interview on information that was gathered during observations and direct interviews with residents and staff.

Documentation – *Use form CMS-807 to record each observation and interview conducted with residents/ parents/ legal guardians and staff. Clearly delineate the documentation as an interview. Include the date and time of each interview and the following information in every recorded entry:*

Resident:

- *The record number, any resident-identifier codes used as a reference to protect the resident's confidentiality, and the resident's age;*
- *Dates of restraint, seclusion or time out; and,*
- *Summary of information obtained.*

Parent/ Legal Guardian:

- *Relationship to the resident;*
- *Method of interview (face-to-face or telephone contact); and,*
- *Summary of information obtained.*

Staff/ Management/ Directors:

- *Position, title and assignment of staff member;*
- *Relationship to the resident or reason for interview; and,*
- *Summary of information obtained.*

2833C.4f TASK 6 - VISIT TO EACH AREA OF THE FACILITY SERVING RESIDENTS

Visit all areas in the facility where residents are permitted to spend their time, both structured and unstructured, as these are places where unanticipated behavior may occur that would require emergency interventions. Also examine the area that is used for restraint as well as those devices that the facility uses as a restraint. Other examples of areas to visit are: restrooms, bathrooms, activity areas, visitation areas, therapy rooms, seclusion/time-out room, dining areas, bedrooms, and classrooms. During the visit or tour, converse with residents and staff. Ask open-ended questions in order to confirm observations, obtain additional information, or corroborate information regarding perceived problems. Observe staff interactions with both residents and other staff members for insight into matters such as individual rights and staff responsibilities.

Protocol - After residents in the sample have been assigned to team members, review the facility's map or building layout. Be sure that at least one team member visits each residential and treatment unit prior to completing the survey. The visit or tour can be conducted at any time during the course of the survey. Always obtain permission from the resident before entering his/her room.

2833C.4g TASK 7 – COMPLIANCE DETERMINATION AND PREPARATION FOR EXIT CONFERENCE

Preparation for Exit Conference.—In preparation for an exit conference, the surveyors should hold a pre-exit survey team conference at the conclusion of the survey and prior to the facility exit conference. The survey team leader must ascertain that all survey team members have completed their respective survey tasks before the pre-exit meeting. At this meeting, the surveyors will share their respective findings, and make team decisions regarding compliance with each standard, requirement, and Condition of Participation. Deficiencies found in more than one aspect of the CoP may be cumulative and interrelated and result in general or across-the-board inadequacies in resident care that may constitute actual or potential hazards to residents. The team leader should record the survey team decisions on the CMS-807 as a record of the team's non-compliance determinations. This would be the basis for a finding of noncompliance. All necessary forms must be completed, which may include:

CMS-807 - Surveyor Notes Worksheet

*CMS-2567 - Statement of deficiencies and Plan of Correction (Post Survey)
And if applicable*

*CMS-726 - CMS Death Record Review Data Sheet
Optional*

CMS-3070I - Individual Observation Worksheet

General - It is recommended to complete the CMS-2567 as a post survey document. Include in the CMS-2567 all examples of evidence obtained from observations,

interviews, and record reviews that contribute to a determination that the facility is deficient in a certain area.

Special Circumstances - If at any time during the survey one or more team members identify a possible immediate jeopardy, the team should meet immediately to confer. See Appendix Q for the definition of and for guidance regarding determination of immediate jeopardy.

***Exit Conference.** — Following the survey team meeting to determine compliance, the survey team should conduct an exit conference with the PRTF’s administrator, designee, and other invited staff. The purpose of the exit conference is to communicate preliminary survey team findings.*

Although it is CMS’ general policy to conduct an exit conference, be aware of situations that may justify discontinuation of an exit conference. For example, if the PRTF is represented by a lawyer (all participants in the exit conference should identify themselves), surveyors may refuse to conduct or continue with the exit conference if the facility lawyer tries to turn it into an evidentiary hearing, or the staff creates an environment that is hostile, overly intimidating, or inconsistent with the informal and preliminary nature of an exit conference. Refer to §2724 of the SOM.

2834 – Other Applicable SOM Sections

The following procedures already established in various Chapters within this manual serve as a basis for direction for the SA.

- *SOM §3010: Termination Procedures – Immediate and Serious Threat to Patient Health and Safety (23 Calendar Days).*
- *SOM §3012: Termination Procedures – Noncompliance with one or more CoPs or Conditions for Coverage and Cited Deficiencies Limit Capacity of Provider/Supplier to Furnish Adequate Level or Quality of Care (90 Calendar Days).*
- *SOM §3060: Appeals of Adverse Actions for Medicaid Non-State operated NFs (Non-State Operated) and ICF/IIDs (Not Applicable to Federal Termination of Medicaid Facilities)*
- *SOM §5200 Investigation of Complaints Against Other than Accredited Providers and Suppliers. Although on its face this section applies to non-accredited providers and suppliers, we believe this section is better suited for PRTFS.*
- *Appendix Q – Guidelines for Determining Immediate Jeopardy – “these guidelines apply to all certified Medicare/Medicaid entities...and to all types of surveys and investigations...”*
- *SOM §4009 Federal Surveyors Qualification Standards*

CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal

Date:

SUBJECT: Appendix N- Psychiatric Residential Treatment Facilities (PRTF) Interpretive Guidance has been added to the State Operations Manual (SOM)

I. SUMMARY OF CHANGES: The SOM has added Appendix N- PRTF Interpretive Guidance.

NEW/REVISED MATERIAL - **EFFECTIVE DATE*:** Upon Issuance
IMPLEMENTATION DATE: Upon Issuance

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N	Appendix N/Psychiatric Residential Treatment Facilities (PRTF) Interpretive Guidelines/Entire Appendix

III. FUNDING: No additional funding will be provided by CMS; State activities are to be carried out within their FY 2015 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

State Operations Manual
Appendix N-Psychiatric Residential Treatment Facilities
(PRTF) Interpretive Guidance

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Transmittals for Appendix N

Appendix N- Psychiatric Residential Treatment Facilities (PRTF)
Interpretive Guidance

483./subpart G/ Condition of Participation for the Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services for Individuals Under Age Twenty One.

§483.350/ Basis and Scope

§483.352/ Definitions

§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.

§441.151 Beneficiary and Accreditation Requirements

(a) Inpatient psychiatric services for individuals under age 21 must be:

(1) Provided under the direction of a physician

(2) Provided by-

(i) A psychiatric hospital that undergoes a State survey to determine whether the hospital meets the requirements for participation in Medicare as a psychiatric hospital as specified in § 482.60 of this chapter, or is accredited by a national organization whose psychiatric hospital accrediting program has been approved by CMS; or a hospital with an inpatient psychiatric program that undergoes a State survey to determine whether the hospital meets the requirements for participation in Medicare as a hospital, as specified in part 482 of this chapter, or is accredited by a national accrediting organization whose hospital accrediting program has been approved by CMS.

(ii) A psychiatric facility that is not a hospital and is accredited by the Joint Commission on Accreditation of healthcare organizations, the Commission on Accreditation of Rehabilitation Facilities, the Council of Accreditation Services for Families and Children, or by any other accrediting organization with comparable standards that is recognized by the State.

(3) Provided before the individual reaches age 21, or, if the individual was receiving services immediately before he or she reached age 21, before the earlier of the following-

(i) The date the individual no longer requires services; or

(ii) The date the individual reaches 22; and

(4) Certified in writing to be necessary in the setting in which the services will be provided (or are being provided in emergency circumstances) in accordance with

§441.152.

(b) Inpatient psychiatric services furnished in a psychiatric residential treatment facility as defined in §483.352 of this chapter, must satisfy all requirements in subpart G of part 483 of this chapter governing the use of restraint and seclusion.

§441.152 -Certification of need for services.

(a) A team specified in 441.154 must certify that-

(1) Ambulatory care resources available in the community do not meet treatment needs of the beneficiary;

(2) Proper treatment of the beneficiary's psychiatric condition requires services on an inpatient basis under the direction of a physician; and

(3) The services can reasonably be expected to improve the beneficiary's condition or prevent further regression so that the services will no longer be needed.

(b) [Paragraph applies to utilization control requirement for physicians – Not to be surveyed by SA – for review of facility]

§441.153 - The team certifying need for services.

Certification under §441.152 must be made by terms specified as follows:

(a) For an individual who is a beneficiary when admitted to a facility or program, certification must be made by an independent team that-

(1) Includes a physician;

(2) Has competence in diagnosis and treatment of mental illness, preferably child psychiatry, and

(3) Has knowledge of the individual's situation.

(b) For an individual who applies for Medicaid while in the facility or program, the certification must be-

(1) Made by the team responsible for the plan of care as specified in 441.156; and

(2) Cover any period before application for which claims are made.

(c) For emergency admissions, the certification must be made by the team responsible for the plan of care (441.156) within 14 days after admission.

§441.154 - Active treatment.

Inpatient psychiatric services must involve "active treatment", which means implementation of a professionally developed and supervised individual plan of care, described in §441.155 that is-

(a) Developed and implemented no later than 14 days after admission; and

(b) Designed to achieve the beneficiary's discharge from in patient status at the earliest possible time.

§441.155 - Individual plan of care.

(a) "Individual plan of care" means a written plan developed for each beneficiary in accordance with §456.180 and §456.181 of this chapter, to improve his condition to the extent that inpatient care is no longer necessary.

(b) The plan of care must-

- (1) Be based on a diagnostic evaluation that includes examination of the medical, psychological, social, behavioral, and developmental aspects of the beneficiary's situation, and reflects the need for inpatient psychiatric care;*
- (2) Be developed by a team of professional specified under §441.156 in consultation with the beneficiary; and his parents, legal guardians, or others in whose care he will be released after discharge;*
- (3) State treatment objectives;*
- (4) Prescribe an integrated program of therapies, activities, and experiences designed to meet the objectives; and*
- (5) Include, at an appropriate time, post-discharge plans and coordination of inpatient services with partial discharge plans and related community services to ensure continuity of care with the beneficiary's family, school, and community upon discharge.*
- (c) The plan must be reviewed every 30 days by the team specified in §441.156 to-*
 - (1) Determine the services being provided are or were required on an inpatient basis, and*
 - (2) Recommend changes in the plan as indicated by the beneficiary's overall adjustment as an inpatient.*
- (d) The development and review of the plan of care as specified in this section satisfies the utilization control requirements for – [paragraph and subparagraphs (1) and (2) relevant for utilization control hospitals only]*

§441.156 Team developing individual plan of care.

- (a) The individual plan of care under §441.155 must be developed by an interdisciplinary team of physicians and other personnel who are employed by, or provide services to patients in, the facility.*
- (b) Based on education and experience, preferably including competence in child psychiatry, the team must be capable of-*
 - (1) Assessing the beneficiary's immediate and long-range therapeutic needs, developmental priorities, and personal strengths and liabilities;*
 - (2) Assessing the potential resources of the beneficiary's family;*
 - (3) Setting treatment objectives; and*
 - (4) Prescribing therapeutic modalities to achieve the plan's objectives.*
- (c) The team must include, as a minimum, either-*
 - (1) A Board-eligible or Board-certified psychiatrist;*
 - (2) A clinical psychologist who has a doctoral degree and a physician licensed to practice medicine or osteopathy; or*
 - (3) A physician licensed to practice medicine or osteopathy with specialized training and experience in the diagnosis and treatment of mental diseases, and a psychologist who has a master's degree in clinical psychology or who has been certified by the State or by the State psychological association.*
- (d) The team must also include one of the following:*
 - (1) A psychiatric social worker.*
 - (2) A registered nurse with specialized training or one year's experience in treating mentally ill individuals.*

(3) An occupational therapist who is licensed, if required by the State, and who has specialized training or one year of experience in treating mentally ill individuals.

(4) A psychologist who has a master's degree in clinical psychology or who has been certified by the State or by the State psychological association.

§441.180 and §441.182 – Maintenance of Effort – Requirements of SMA.

§483.356/ Protection of Residents.

§483.356(a)/ Restraint and seclusion policy for the protection of residents

§483.356(a)(1)/ Protection of Residents-Each resident has the right to be free from restraint and seclusion, of any form, used as a means of coercion, discipline, convenience, or retaliation.

§483.356(a)(2)/ An order for restraint or seclusion must not be written as a standing order or on an as-needed basis.

§483.356(a)(3)/ Restraint or seclusion must not result in harm or injury to the resident and must be used only-

§483.356(a)(3)(i)/ To ensure the safety of the resident or others during an emergency safety situation; and

§483.356(a)(3)(ii)/ Until the emergency situation has ceased and the resident's safety and the safety of others can be ensured, even if the restraint or seclusion order has not expired.

§483.356(a)(4)/ Restraint and seclusion must not be used simultaneously

§483.356(b)/ Emergency safety intervention. An emergency safety intervention must be performed in a manner that is safe, proportionate, and appropriate to the severity of the behavior, and the resident's chronological and developmental age; size; gender; physical, medical, and psychiatric condition; and personal history (including any history of physical or sexual abuse).

§483.356(c)(1)/ Notification of facility policy. At admission, the facility must: Inform both the incoming resident and, in the case of a minor, the resident's parent(s) or legal guardian(s) of the facility's policy regarding the use of restraint or seclusion during an emergency safety situation that may occur while the resident is in the program;

§483.356(c)(2)/ Communicate its restraint and seclusion policy in a language that the resident, or his or her parent(s) or legal guardian(s) understands (including American Sign Language, if appropriate) and when necessary, the facility must provide interpreters or translators;

§483.356(c)(3)/ Obtain an acknowledgment, in writing, from the resident, or in the case of a minor, from the parent(s) or legal guardian(s) that he or she has been informed of the facility's policy on the use of restraint or seclusion during an emergency safety situation. Staff must file this acknowledgment in the resident's record; and

§483.356(c)(4)/ Provide a copy of the facility policy to the resident and in the case of a minor, to the resident's parent(s) or legal guardian(s).

§483.356(d)/ Contact information. The facility's policy must provide contact information, including the phone number and mailing address, for the appropriate State Protection and Advocacy organization.

§483.358/ Orders for use of restraint or seclusion.

§483.358(a)/ Orders for restraint or seclusion must be by a physician, or other licensed practitioner permitted by the State and the facility to order restraint or seclusion and trained in the use of emergency safety interventions. Federal regulations at 42 CFR 441.151 require that inpatient psychiatric services for beneficiaries under age 21 are provided under the direction of a physician.

§483.358(b)/ If the resident's treatment team physician is available, only he or she can order restraint or seclusion.

§483.358(c)/ A physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion must order the least restrictive emergency safety intervention that is most likely to be effective in resolving the emergency safety situation based on consultation with staff.

§483.358(d)/ If the order for restraint or seclusion is verbal, the verbal order must be received by a registered nurse or other licensed staff such as a licensed practical nurse, while the emergency safety intervention is being initiated by staff or immediately after the emergency safety situation ends. The physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion must verify the verbal order in a signed written form in the resident's record. The physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion must be available to staff for consultation, at least by telephone, throughout the period of the emergency safety intervention.

§483.358(e)/ Each order for restraint or seclusion must:

- (1) Be limited to no longer than the duration of the emergency safety situation; and*
- (2) Under no circumstances exceed 4 hours for residents ages 18 to 21; 2 hours for residents' ages 9 to 17; or 1 hour for residents under age 9.*

§483.358(f)/ Within 1 hour of the initiation of the emergency safety intervention a physician, or other licensed practitioner trained in the use of emergency safety interventions and permitted by the state and the facility to assess the physical and psychological well being of residents, must conduct a face-to-face assessment of the physical and psychological well being of the resident, including but not limited to—

- (1) The resident's physical and psychological status;*
- (2) The resident's behavior;*
- (3) The appropriateness of the intervention measures; and*
- (4) Any complications resulting from the intervention.*

§483.358(g)/ Each order for restraint or seclusion must include-

§483.358(g)(1)/ The name of the ordering physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion;

§483.358(g)(2)/ The date and time the order was obtained; and

§483.358(g)(3)/ The emergency safety intervention ordered, including the length of time for which the physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion authorized its use.

§483.358(h)/ Staff must document the intervention in the resident's record. That

documentation must be completed by the end of the shift in which the intervention occurs. If the intervention does not end during the shift in which it began, documentation must be completed during the shift in which it ends.

Documentation must include all of the following:

§483.358(h)(1)/ Each order for restraint or seclusion as required in paragraph (g) of this section.

§483.358(h)(2)/ The time the emergency safety intervention actually began and ended.

§483.358(h)(3)/ The time and results of the 1-hour assessment required in paragraph (f) of this section.

§483.358(h)(4)/ The emergency safety situation that required the resident to be restrained or put in seclusion.

§483.358(h)(5)/ The name of staff involved in the emergency safety intervention.

§483.358(i)/ The facility must maintain a record of each emergency safety situation, the interventions used, and their outcomes.

§483.358(j)/ The physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion must sign the restraint or seclusion order in the resident's record as soon as possible.

§483.360/ Consultation with treatment team physician. If a physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion orders the use of restraint or seclusion, that person must contact the resident's treatment team physician, unless the ordering physician is in fact the resident's treatment team physician. The person ordering the use of restraint or seclusion must—

§483.360(a)/ Consult with the resident's treatment team physician as soon as possible and inform the team physician of the emergency safety situation that required the resident to be restrained or placed in seclusion; and Protection of Residents—Each resident has the right to be free from restraint and seclusion, of any form, used as a means of coercion, discipline, convenience, or retaliation.

§483.360(b)/ Document in the resident's record the date and time the team physician was consulted.

§483.362/ Monitoring of the resident in and immediately after restraint.

§483.362(a)/ Clinical staff trained in the use of emergency safety interventions must be physically present, continually assessing, and monitoring the physical and psychological well-being of the resident and the safe use of restraint throughout the duration of the emergency safety intervention.

§483.362(b)/ If the emergency safety situation continues beyond the time limit of the order for the use of restraint, a registered nurse or other licensed staff, such as a licensed practical nurse, must immediately contact the ordering physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion to receive further instructions.

§483.362(c)/ A physician, or other licensed practitioner permitted by the state and the facility to evaluate the resident's well-being and trained in the use of emergency safety interventions, must evaluate the resident's well being immediately after the restraint is removed.

§483.364/ Monitoring of the resident in and immediately after seclusion.

§483.364(a)/ Clinical staff, trained in the use of emergency safety interventions, must be physically present in or immediately outside the seclusion room, continually assessing, monitoring, and evaluating the physical and psychological well being of the resident in seclusion. Video monitoring does not meet this requirement.

§483.364(b)/ A room used for seclusion must—

§483.364(b)(1)/ Allow staff full view of the resident in all areas of the room; and

§483.364(b)(2)/ Be free of potentially hazardous conditions such as unprotected light fixtures and electrical outlets.

§483.364(c)/ If the emergency safety situation continues beyond the time limit of the order for the use of seclusion, a registered nurse or other licensed staff, such as a licensed practical nurse, must immediately contact the ordering physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion to receive further instructions.

§483.364(d)/ A physician, or other licensed practitioner permitted by the state and the facility to evaluate the resident's well being and trained in the use of emergency safety interventions, must evaluate the resident's well-being immediately after the resident is removed from seclusion.

§483.366/ Notification of parent(s) or legal guardian(s). If the resident is a minor as defined in this subpart:

§483.366(a)/ The facility must notify the parent(s) or legal guardian(s) of the resident who has been restrained or placed in seclusion as soon as possible after the initiation of each emergency safety intervention.

§483.366(b)/ The facility must document in the resident's record that the parent(s) or legal guardian(s) has been notified of the emergency safety intervention, including the date and time of notification and the name of the staff person providing the notification.

§483.368/ Application of time out

§483.368(a)/ A resident in time out must never be physically prevented from leaving the time out area.

§483.368(b)/ Time out may take place away from the area of activity or from other residents, such as in the resident's room (exclusionary), or in the area of activity of other residents (inclusionary)?

§483.368(c)/ Staff must monitor the resident while he or she is in time out.

§483.370/ Post intervention debriefings.

§483.370(a)/ Within 24 hours after the use of the restraint or seclusion, staff involved in an emergency safety intervention and the resident must have a face-to-face discussion.

This discussion must include all staff involved in the intervention except when the presence of a particular staff person may jeopardize the well being of the resident.

Other staff and the resident's parent(s) or legal guardian(s) may participate in the discussion when it is deemed appropriate by the facility.

The facility must conduct such discussion in a language that is understood by the resident's parent(s) or legal guardian(s).

The discussion must provide both the resident and staff the opportunity to discuss

the circumstances resulting in the use of restraint or seclusion and strategies to be used by the staff, the resident, or others that could prevent the future use of restraint or seclusion.

§483.370(b)/ Within 24 hours after the use of restraint or seclusion, all staff involved in the emergency safety intervention, and appropriate supervisory and administrative staff, must conduct a debriefing session that includes, at a minimum, a review and discussion of –

§483.370(b)(1) the emergency safety situation that required the intervention, including discussion of the precipitating factors that led up to the intervention;

§483.370(b)(2) Alternative techniques that might have prevented the use of the restraint or seclusion;

§483.370(b)(3) The procedures, if any, that staff are to implement to prevent any recurrence of the use of restraint or seclusion; and

§483.370(b)(4) The outcome of the intervention, including any injuries that may have resulted from the use of restraint or seclusion.

§483.370(c)/ Staff must document in the resident’s record that both debriefing sessions took place and must include in that documentation:

The names of staff who were present for the debriefing,

The names of staff who were excused from the debriefing, and

Any changes to the resident’s treatment plan that result from the debriefings.

483.372/ Medical Treatment for injuries resulting from an emergency safety intervention.

§483.372(a)/ Staff must immediately obtain medical treatment from qualified medical personnel for a resident injured as a result of an emergency safety intervention.

§483.372(b)/ The psychiatric residential treatment facility must have affiliations or written transfer agreements in effect with one or more hospitals approved for participation under the Medicaid program that reasonably ensure that—

§483.372(b)(1) A resident will be transferred from the facility to a hospital and admitted in a timely manner when a transfer is medically necessary for medical care or acute psychiatric care;

§483.372(b)(2) Medical and other information needed for care of the resident in light of such a transfer, will be exchanged between the institutions in accordance with State medical privacy law, including any information needed to determine whether the appropriate care can be provided in a less restrictive setting; and

§483.372(b)(3) Services are available to each resident 24 hours a day, 7 days a week.

§483.372(c)/ Staff must document in the resident’s record, all injuries that occur as a result of an emergency safety intervention, including injuries to staff resulting from that intervention.

§483.372(d)/ Staff involved in an emergency safety intervention that results in an injury to a resident or staff must meet with supervisory staff and evaluate the circumstances that caused the injury and develop a plan to prevent future injuries.

483.374/ Facility Reporting

§483.374(a)/ Attestation of facility compliance.

Each psychiatric residential treatment facility that provides inpatient psychiatric services to individuals under age 21 must attest, in writing, that the facility is in compliance with CMS' standards governing the use of restraint and seclusion.

This attestation must be signed by the facility director.

§483.374(a)(1)/ A facility with a current provider agreement with the Medicaid agency must provide its attestation to the State Medicaid agency by July 21, 2001.

(2) A facility enrolling as a Medicaid provider must meet this requirement at the time it executes a provider agreement with the Medicaid agency.

§483.374(b)/ Reporting of serious occurrences.

The facility must report each serious occurrence to both the State Medicaid agency and, unless prohibited by State law, the State designated Protection and Advocacy system. Serious occurrences that must be reported include a resident's death, a serious injury to a resident as defined in section §483.352 of this part, and a resident's suicide attempt.

(1) Staff must report any serious occurrence involving a resident to both the State Medicaid agency and the State designated Protection and Advocacy system by no later than close of business the next business day after a serious occurrence. The report must include the name of the resident involved in the serious occurrence, a description of the occurrence and, the name, street address, and telephone number of the facility.

§483.374(b)(2)/ In the case of a minor, the facility must notify the resident's parent(s) or legal guardian(s) as soon as possible, and in no case later than 24 hours after the serious occurrence.

§483.374(b)(3)/ Staff must document in the resident's record that the serious occurrence was reported to both the State Medicaid agency and the State designated Protection and Advocacy system, including the name of the person to whom the incident was reported. A copy of the report must be maintained in the resident's record, as well as in the incident and accident report logs kept by the facility.

§483.374(c)/ Reporting of deaths. In addition to the reporting requirements contained in paragraph (b) of this section, facilities must report the death of any resident to the Centers for Medicare and Medicaid Services (CMS) regional office.

(1) Staff must report the death of any resident to the CMS regional office by no later than close of business the next business day after the resident's death.

(2) Staff must document in the resident's record that the death was reported to the CMS regional office.

483.376/Education and Training

§483.376(a)/ The facility must require staff to have ongoing education, training, and demonstrated knowledge of –

§483.376(a)(1)/ Techniques to identify staff and resident behaviors, events, and environmental factors that may trigger emergency safety situations;

§483.376(a)(2)/ The use of nonphysical intervention skills, such as de-

escalation, mediation conflict resolution, active listening, and verbal and observational methods, to prevent emergency safety situations; and §483.376(a)(3)/ The safe use of restraint and the safe use of seclusion, including the ability to recognize and respond to signs of physical distress in residents who are restrained or in seclusion.

§483.376(b)/ Certification in the use of cardiopulmonary resuscitation, including periodic recertification, is required.

§483.376(c)/ Individuals who are qualified by education, training and experience must provide staff training.

§483.376(d)/ Staff training must include training exercises in which staff members successfully demonstrate in practice the techniques they have learned for managing emergency safety situations.

§483.376(e)/ Staff must be trained and demonstrate competency before participating in an emergency safety situation.

§483.376(f)/ Staff must demonstrate their competencies as specified in paragraph (a) of this section on a semiannual basis and their competencies as specified in paragraph (b) of this section on an annual basis.

§483.376(g)/ The facility must document in the staff personnel records that the training and demonstration of competency were successfully completed. Documentation must include the date training was completed and the name of persons certifying the completion of training.

§483.376(h)/ All training programs and materials used by the facility must be available for review by CMS, the State Medicaid agency, and the State survey agency.

Regulation

N0100

(Rev.)

Subpart G: Condition of Participation for the Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services for Individuals Under Age Twenty One.

Interpretive Guidelines Subpart G

Surveyors must make a determination regarding the compliance or non-compliance of the overall Condition of Participation under Subpart G at the end of each facility survey. A determination of non-compliance may be based upon either patterns of performance or isolated instances with real or potential harm for residents. Deficiencies cited in the following areas:

Section 483.354 General requirements for psychiatric residential treatment facilities

Section 483.356 Protection of Residents;

Section 483.358 Orders for the use of restraint or seclusion;

Section 483.372 Medicaid treatment for injuries resulting from an emergency safety intervention,

Section 483.374 Facility Reporting and/or

Section 483.376 Education and Training

Surveyors should consider the seriousness and significance of the aggregate findings in the survey areas when determining any non-compliance at a Condition level. If the determination is made that the facility is out of compliance with the Condition of Participation, the surveyor must make this finding at N-0100. The determination must include a list of the N tag findings which resulted in the Condition non-compliance to be made.

§483.350 Basis and Scope

(Rev.)

- (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.

(Rev.)

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.

N0101-N0119

(Rev.)

§483.354 General requirements for psychiatric residential treatment facilities.

(Rev.)

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

Interpretive Guidelines§483.354

Surveyors should reference guidelines for requirements §441.151 through §441.182 in the ASPEN system.

§ 483.356 Protection of Residents.

(Rev.)

N0125

(Rev.)

§ 483.356(a) Restraint and seclusion policy for the protection of residents.

Interpretive Guidelines§ 483.356(a)

The use of restraint and seclusion as described in this Condition of Participation (COP) applies to all residents of the Psychiatric Residential Treatment Facilities (PRTFs) (i.e., children and individuals under the age of 21).

The facility must establish a policy for the use of restraint and seclusion. The policy must address emergency safety intervention (ESI), which is defined in this subpart as the use of restraint or seclusion as an immediate response to an emergency safety situation. In

addition, the facility policy should include, at a minimum, the facility's procedures regarding all the requirements as set forth in this COP.

N0126

(Rev.)

§ 483.356(a)(1) Each resident has the right to be free from restraint or seclusion, of any form, used as a means of coercion, discipline, convenience, or retaliation.

Interpretive Guidelines § 483.356(a)(1)

Restraint or seclusion, including drugs/medications used as restraint, is not to be used as coercion, discipline, convenience, or retaliation.

- 1. Discipline - Restraint and seclusion are never to be used as a means to punish or penalize a resident for the purpose of controlling behavior.*
- 2. Coercion – (depriving the resident of the exercise of his/her free will by the use or threat of physical or emotional force.) Staff may not use intimidation to prevent an individual from free movement or verbal expression. .*
- 3. Convenience – (for the staff or facility) Staff may not employ restraint or seclusion as a compensation for inadequate number of trained staff or programming.*
- 4. Retaliation- Staff or facility practice must never use restraint or seclusion as a means to retaliate against a resident for any reason.
The frequent use of emergency safety interventions may raise serious questions about the resident's right to be free from unnecessary restraint or seclusion and indicate the need for further investigation by the surveyor.*

N0127

(Rev.)

§483.356(a)(2) An order for restraint or seclusion must not be written as a standing order or on an as-needed basis.

Interpretive Guidelines § 483.356(a)(2)

The use of restraint or seclusion must not be a planned or anticipated intervention. Active treatment does not include the routine use of restraint and seclusion. There should not be a specific plan in place for restraints and seclusion but the facility must have policies on the process if action is necessary and have facility procedures in place for implementation. In order to ensure a resident receives active treatment and is free from abuse, it is necessary that a physician or other licensed practitioners' order be given for each single instance of restraint or seclusion (as indicated by individual state law).

N0128
(Rev.)

§483.356(a)(3) Restraint or seclusion must not result in harm or injury to the resident and must be used only—

Interpretive Guidelines § 483.356(a)(3)

Identify any restraint or seclusion involving harm or injury to the resident during the restraint or seclusion episode.

While reviewing reports surveyors should be cognizant of what types of restraint or seclusion is being used by the facility and how restraints are applied. The following types of restraints are prohibited in a PRTF:

- 1. Restraints that may impair the breathing (obstructing the airways of the resident by putting pressure on the back or chest of the individual);*
- 2. Restraints that restrict the resident's ability to communicate during an emergency safety intervention.*

N0129
(Rev.)

§483.356(a)(3)(i) To ensure the safety of the resident or others during an emergency safety situation; and

Interpretive Guidelines § 483.356(a)(3)(i)

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

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

An ESI is to be used only in response to an emergency safety situation. It is not a preventative measure, but is a reaction to an emergency safety situation that cannot be contained with any less restrictive measures. The emergency safety intervention is the most restrictive measure and is used as the last resort to ensure the safety of the resident and others.

N0130
(Rev.)

§483.356(a)(3)(ii) Until the emergency safety situation has ceased and the resident's safety and the safety of others can be ensured, even if the restraint or seclusion order has not expired.

Interpretive Guidelines § 483.356(a)(3)(ii)

The resident in restraint or seclusion should be evaluated on a continual basis (see N-0165 and N-0166 for continual monitoring criteria) and ended at the earliest possible time based on the assessment and evaluation of the resident's condition.

Restraint or seclusion intervention must be discontinued if the safety situation has ceased and the safety of the resident and others can be ensured, even when the physician order for the restraint or seclusion has not expired. For example, if a resident has recovered from their unanticipated maladaptive behavior in 2-hours instead of the maximum 4-hour time frame specified in the order, it is the expectation that the resident is released from restraint or seclusion at the 2-hour point. The facility policy for restraints and seclusion should outline the criteria for discontinuing ESI interventions.

***N0131
(Rev.)***

§483.356(a)(4) Restraint and seclusion must not be used simultaneously.

Interpretive Guidelines § 483.356(a)(4)

The facility must not utilize restraint, including drugs/medications used as restraint at the same time as utilizing seclusion.

There may be isolated instances where both physical and psychopharmacological restraints are required during one emergency safety situation. In addition, the risk(s) associated with any drug/medication used as a restraint must be weighed against the type and severity of the behavior the resident is exhibiting. The resident record must include documentation to explain why the first restraint was insufficient and the second restraint was added.

If restraint is necessary as a means of safely transporting the resident to seclusion, a separate order is not required. However, the initial order for the seclusion must include the physical transport restraint and be consistent with the requirements for restraint/seclusion orders.

***N0132
(Rev.)***

§483.356(b). Emergency safety intervention. An emergency safety intervention must be performed in a manner that is safe, proportionate, and appropriate to the severity of

the behavior, and the resident's chronological and developmental age; size; gender; physical, medical, and psychiatric condition; and personal history (including any history of physical or sexual abuse).

Interpretive Guidelines § 483.356(b)

Review of resident records to determine if the intervention that was implemented took into account the resident's:

- 1. Chronological and developmental age;*
- 2. Size;*
- 3. Gender;*
- 4. Physical, medical, and psychiatric condition; and*
- 5. Personal history (either in treatment plan or treatment notes) (including any history of physical, mental, sexual abuse or trauma)*

N0133

(Rev.)

§483.356(c) Notification of facility policy. At admission, the facility must—

§483.356(c)(1) Inform both the incoming resident and, in the case of a minor, the resident's parent(s) or legal guardian(s) of the facility's policy regarding the use of restraint or seclusion during an emergency safety situation that may occur while the resident is in the program;

Interpretive Guidelines § 483.356(c)(1)

Under subpart 483.352(3), “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.” The facility must ensure that its policies on restraint and seclusion are discussed at the time of admission and the resident and/or their guardian signs to indicate they received the information (a copy of the policy provided to them) and understood the information provided.

N0134

(Rev.)

§483.356(c)(2) Communicate its restraint and seclusion policy in a language that the resident, or his or her parent(s) or legal guardian(s) understands (including American Sign Language, if appropriate) and when necessary, the facility must provide interpreters or translators;

Interpretive Guidelines § 483.356(c)(2)

During the process of resident record reviews note any instances where a communication barrier was identified for either the resident or the legal guardian. Review the

corresponding documentation of the information provided at the time of admission concerning the facility policies on restraint and seclusion. Ensure that any communication barriers were addressed.

N0135

(Rev.)

§483.356(c)(3) [At admission, the facility must] obtain an acknowledgment, in writing, from the resident, or in the case of a minor, from the parent(s) or legal guardian(s) that he or she has been informed of the facility's policy on the use of restraint or seclusion during an emergency safety situation. Staff must file this acknowledgment in the resident's record; and

Interpretive Guidelines § 483.356(c)(3)

See Interpretive Guidance for §483.356(c)(1).

N0136

(Rev.)

§483.356(c)(4) [At admission, the facility must] provide a copy of the facility policy to the resident and in the case of a minor, to the resident's parent(s) or legal guardian(s).

Interpretive Guidelines § 483.356(c)(4)

See Interpretive Guidance for §483.356(c)(1).

N0137

(Rev.)

§483.356(d) Contact information. The facility's policy must provide contact information, including the phone number and mailing address, for the appropriate State Protection and Advocacy organization.

Interpretive Guidelines § 483.356(d)

This written information must be provided to the resident and/ or parent/ legal guardian upon admission. The contact information must be presented in a manner and language understandable to the resident. If the facility is unsure of which State Protection and Advocacy (P&A) organization to refer the resident to, the facility may provide the contact information for the national P&A organization.

§483.358 Orders for the use of restraint or seclusion.

(Rev.)

N0140

(Rev.)

§483.358(a) Orders for restraint or seclusion must be by a physician, or other licensed practitioner permitted by the State and the facility to order restraint or seclusion and trained in the use of emergency safety interventions. Federal regulations at 42 CFR 441.151 require that inpatient psychiatric services for beneficiaries under age 21 are provided under the direction of a physician.

Interpretive Guidelines § 483.358(a)

The facility's policy should indicate (in conformity with applicable state law), what licensed health care practitioners may order the use of restraint or seclusion in the facility. The policies should also state the types, amounts and frequency of training required for these practitioners in the area of emergency safety interventions. Reference §483.376 Education and Training, tags N-0214-N-0224 below

**N0141
(Rev.)**

§483.358(b) If the resident's treatment team physician is available, only he or she can order restraint or seclusion.

Interpretive Guidelines § 483.358(b)

The treatment team physician is the physician who is responsible for the management and care of the resident. If the treating physician does not give the order for the emergency intervention, it is important that the facility staff consult with the treating physician, as soon as he/she is available, because information regarding the resident's history may have a significant impact on the selection of seclusion or restraint intervention. If the physician ordering the use of restraint and seclusion is not the resident's treatment team physician, then the ordering physician or other licensed practitioner must consult with the resident's treatment team physician as soon as possible from the time the order was given by the alternate practitioner and in a signed written form in the resident's record.

**N0142
(Rev.)**

§483.358(c) A physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion must order the least restrictive emergency safety intervention that is most likely to be effective in resolving the emergency safety situation based on consultation with staff.

Interpretive Guidelines § 483.358(c)

The restraint or seclusion used must be appropriate for both the resident and the situation. The treatment plan should address any contraindications or inappropriate interventions for the resident. A medication that is not being used as a standard treatment

for the resident's medical or psychiatric condition that results in controlling the resident's behavior and/or in restricting his or her freedom of movement is considered a restraint.

Example: Staff use of physical restraint hold for a resident who is verbally abusive and/or escalating without having utilized other non-physical de-escalation techniques would be considered as not appropriate or not least restrictive. Verbal de-escalation techniques and decrease in physical environmental stimuli would be considered least restrictive. Use of any physical intervention would be considered counter therapeutic, and potentially traumatic, for victims of physical or sexual abuse.

The residents' treatment plan should indicate the least restrictive interventions to help the resident and treatment staff in the case of emergency situations where an unanticipated behavior requires immediate protection of the individual or others. Documentation in the residents medical record should detail the less restrictive measures utilized prior to the application of the restraint or seclusion.

Staff should document interventions that have been attempted prior to implementing seclusion or restraint. The effectiveness or ineffectiveness of interventions should be evaluated and incorporated into the resident's treatment plan and these should also be used as a basis for planning for future interventions.

N0143
(Rev.)

§483.358(d) If the order for restraint or seclusion is verbal, the verbal order must be received by a registered nurse or other licensed staff such as a licensed practical nurse, while the emergency safety intervention is being initiated by staff or immediately after the emergency safety situation ends. The physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion must verify the verbal order in a signed written form in the resident's record. The physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion must be available to staff for consultation, at least by telephone, throughout the period of the emergency safety intervention.

Interpretive Guidelines § 483.358(d)

The facility's policy should conform to state law regarding the receipt of verbal orders. The policy should also indicate who, other than a registered nurse, may receive a verbal order for restraint or seclusion. The verbal order can only be received by a registered nurse or other licensed staff. If the facility identifies "other licensed staff" this should conform to state law. The policy should also include the timeframe in which a physician or other licensed practitioner must co-sign the verbal order.

N0144
(Rev.)

§483.358(e) Each order for restraint or seclusion must:

- (1) Be limited to no longer than the duration of the emergency safety situation; and**
- (2) Under no circumstances exceed 4 hours for residents ages 18 to 21; 2 hours for residents ages 9 to 17; or 1 hour for residents under age 9.**

Interpretive Guidelines § 483.358(e)

A restraint or seclusion must be used only until the emergency safety situation has ceased and the resident's safety and the safety of others can be ensured, even if the restraint or seclusion order has not expired. The time frames specified in these requirements are maximums per age group. The ordering practitioner has the discretion to decide that the order be written for a shorter period of time. Throughout the restraint or seclusion period staff should be assessing, monitoring, and re-evaluating the resident so that he or she is released from the restraint or seclusion at the earliest possible time.

If restraint or seclusion is discontinued prior to the expiration of the original order, a new order must be obtained prior to reinitiating seclusion or reapplying restraints. At the point in which a new order for restraint or seclusion has been obtained, all requirements for monitoring and documentation begin as with all new orders. Specifically, after a resident has been removed from restraint or seclusion for any amount of time, the next incident of restraint or seclusion may not be considered a continuation of the previous restraint or seclusion order.

N0145

(Rev.)

§483.358(f) Within 1 hour of the initiation of the emergency safety intervention a physician, or other licensed practitioner trained in the use of emergency safety interventions and permitted by the state and the facility to assess the physical and psychological wellbeing of residents, must conduct a face-to-face assessment of the physical and psychological wellbeing of the resident, including but not limited to—

- (1) The resident's physical and psychological status;**
 - (2) The resident's behavior;**
 - (3) The appropriateness of the intervention measures; and**
- (1) Any complications resulting from the intervention.**

Interpretive Guidelines § 483.358(f)

A physician or other licensed practitioner (as recognized by State law and facility policy) such as registered nurses, physician's assistants or nurse practitioners, if it is within the scope of their discipline and licensure, must perform an in person face-to-face evaluation of the resident within one-hour of the initiation of restraint or seclusion. A telephone call

or other electronic communication does not fulfill this requirement. The physician or other licensed practitioner must be physically present to evaluate and assess the status of the resident. The assessment ensures the resident's rights, confirms that the restraint or seclusion is necessary and appropriate and allows the practitioner to evaluate the medical status of the resident.

If a resident is released from restraint or seclusion before the physician or other licensed practitioner arrives to perform the face-to-face assessment, the physician or other licensed practitioner must still conduct the required face-to-face assessment within one hour after the initiation of the intervention.

This face-to-face assessment must be conducted for all types of restraints (including drugs/medications used as a restraint) and seclusion.

N0146
(Rev.)

§483.358(g) Each order for restraint or seclusion must include—

- (1) The name of the ordering physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion;**

Interpretive Guidelines § 483.358(g)(1)

Each order for restraint and seclusion, an order is required regardless of the expected length of time the restraint or seclusion will be used, the type of emergency safety intervention used, or where the emergency safety intervention takes place. The ordering practitioner does not need to be physically present to give the order. However, a licensed practitioner must be available for staff consultation at least by telephone, throughout the entire period of the emergency safety intervention, reference §483.358(d).

Documentation (resident medical record and appropriate logs) must have evidence of all aspects of circumstances, date, time and both licensed and non-licensed staff involved in the emergency safety intervention.

Ensure that the person writing the restraint or seclusion order is appropriately licensed and possesses required qualifications as established by the regulation or relevant state law.

N0147
(Rev.)

§483.358(g)(2) [Each order for restraint or seclusion must include] the date and time the order was obtained; and

Interpretive Guidelines § 483.358(g)(2)

The date and time of the restraint or seclusion order must match with the date and time of the restraint or seclusion intervention.

N0148

(Rev.)

§483.358(g)(3) [Each order for restraint or seclusion must include] the emergency safety intervention ordered, including the length of time for which the physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion authorized its use.

Interpretive Guidelines § 483.358(g)(3)

An order for restraint or seclusion is only valid for one individual behavioral incident. Orders for restraint or seclusion may not be extended. If behaviors continue after the end of one order timeframe a separate order is required.

N0149

(Rev.)

§483.358(h) Staff must document the intervention in the resident's record. That documentation must be completed by the end of the shift in which the intervention occurs. If the intervention does not end during the shift in which it began, documentation must be completed during the shift in which it ends. Documentation must include all of the following:

Interpretive Guidelines § 483.358(h)

Relevant and appropriate staff must fully document the events leading up to, during and after the implementation of restraint or seclusion as specified by §483.358(h)(1-5). This includes documentation of the time in which the emergency safety situation/intervention began, the request and receipt of any practitioner orders for intervention, a complete description of the emergency safety situation, the results of the 1 hour face-to-face assessment, and the names of all staff that were involved with the restraint and seclusion.

If the resident is still restrained or secluded at the end of a shift, the staff person who witnessed the events that led up to the restraint or seclusion is accountable for providing comprehensive documentation in the record of the events that led up to and the implementation of the restraint or seclusion. After the resident has been removed from restraint or seclusion, the staff that is present during the conclusion of the emergency safety intervention is required to document their observations of the resident throughout the duration of the seclusion or restraint and the discontinuation of the safety intervention.

N0150

(Rev.)

§483.358(h)(1) [Documentation must include] each order for restraint or seclusion as required in paragraph (g) of this section.

Interpretive Guidelines § 483.358(h)(1)

”As stated in §483.358(g), Each Order for restraint or seclusion must include- “ through §483.358(g)(3) “The emergency safety intervention ordered, including the length of time for which the physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion authorized its use” and associated Guidance.

N0151

(Rev.)

§483.358(h)(2) [Documentation must include] the time the emergency safety intervention actually began and ended.

N0152

(Rev.)

§483.358(h)(3) [Documentation must include] the time and results of the 1-hour assessment required in paragraph (f) of this section.

Interpretive Guidelines § 483.358(h)(3)

In addition to the information required at N-0145, the assessment should include whether or not the physician or other licensed practitioner advised continuation of the emergency safety intervention or termination of the emergency safety intervention and the documentation justifying the decision. In those cases where only one hour of restraint or seclusion was ordered and the practitioner performing the assessment feels the restraint or seclusion should continue, a new order is required.

N0153

(Rev.)

§483.358(h)(4) [Documentation must include] the emergency safety situation that required the resident to be restrained or put in seclusion.

N0154

(Rev.)

§483.358(h)(5) [Documentation must include] the name of staff involved in the emergency safety intervention.

Interpretive Guidelines § 483.358(h)(5)

The names of all staff members involved in the emergency safety intervention including that of the physician or licensed practitioner who ordered the emergency safety intervention and the practitioner who performed the one hour face-to-face assessment must be documented

Note: Involved staff includes all staff physically participating in the ESI and any staff providing orders or assessments during the ESI.

***N0155
(Rev.)***

§483.358(i) The facility must maintain a record of each emergency safety situation, the interventions used, and their outcomes.

Interpretive Guidelines § 483.358(i)

Verify that the facility maintains a separate, cumulative log of all restraint and seclusions that occur in the facility. Each log entry should be dated and timed and include information concerning the interventions that were used and the ultimate outcome of any associated restraint and seclusion.

Note any instances where resident record review indicated that an restraint or seclusion occurred but was not entered into the log.

***N0156
(Rev.)***

§483.358(j) The physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion must sign the restraint or seclusion order in the resident's record as soon as possible.

Interpretive Guidelines § 483.358(j)

If the ordering physician or other licensed practitioner is not present on the unit at the time the order is given, any verbal order for restraint or seclusion obtained by a registered nurse or other licensed staff, should be signed by the physician or licensed practitioner within 48 hours or in accordance with applicable state law.

***§483.360 Consultation with treatment team physician
(Rev.)***

If a physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion orders the use of restraint or seclusion, that person must contact the resident's treatment team physician, unless the ordering physician is in fact the resident's treatment team physician. The person ordering the use of restraint or seclusion must—

N0160
(Rev.)

§483.360(a) Consult with the resident's treatment team physician as soon as possible and inform the team physician of the emergency safety situation that required the resident to be restrained or placed in seclusion; and

Interpretive Guidelines § 483.360(a)

The treatment team physician is the physician who is responsible for the management and care of the resident on a day-to-day basis. When an alternate practitioner orders restraint or seclusion in lieu of the treatment team physician he/she has an obligation to inform the treatment team physician of the events that transpired and led to the order for an emergency safety intervention and in a signed written form in the resident's record.

They are also responsible for updating the treatment team physician with any complications that may have resulted from the emergency safety intervention and the resident's physical and mental status at the time the report is made. Because the emergency safety intervention/situation and its outcomes may greatly affect the resident's treatment plan, it is important to consult with the treatment team physician, as soon as possible from the time the order was given by the alternate practitioner

N0161
(Rev.)

§483.360(b) Document in the resident's record the date and time the team physician was consulted.

Interpretive Guidelines § 483.360(b)

Documentation of notification of the treatment team physician included in the date and time the physician was notified, the information provided concerning the need for restraint or seclusion, the outcome of the restraint and seclusion

§483.362 Monitoring of the resident in and immediately after Restraint

N0165
(Rev.)

§483.362(a) Clinical staff trained in the use of emergency safety interventions must be physically present, continually assessing, and monitoring the physical and psychological well-being of the resident and the safe use of restraint throughout the duration of the emergency safety intervention.

Interpretive Guidelines § 483.362(a)

“Physically present” should be defined as being in close enough proximity to the resident at all times to be able to verify that the resident is no acute distress from the restraint or seclusion. The staff must be able to assess, at any given moment, the resident’s respirations, hear and respond to resident calls for assistance and observe changes in resident behavior.

“Continually assessing” should be defined as observing, measuring and evaluating at all times and documentation every 5 minutes of the ongoing assessment of the behavior and physical status of the resident by the staff members who are physically present throughout the duration of the restraint or seclusion.

**N0166
(Rev.)**

§483.362(b) If the emergency safety situation continues beyond the time limit of the order for the use of restraint, a registered nurse or other licensed staff, such as a licensed practical nurse, must immediately contact the ordering physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion to receive further instructions.

Interpretive Guidelines § 483.362(b)

If necessary, prior to the expiration of the original order for restraint, a registered nurse or other licensed staff may telephone the physician or other licensed practitioner, report the results of his/her most recent assessment and obtain further instruction. If the practitioner advises that the ESI continue past the limits of the current order, the expectation is that a new order must be obtained, based upon current behaviors.

There must be documentation in the resident record of the behaviors which justified a new order for restraint.

**N0167
(Rev.)**

§483.362(c) A physician, or other licensed practitioner permitted by the state and the facility to evaluate the resident's well-being and trained in the use of emergency safety interventions, must evaluate the resident's well-being immediately after the restraint is removed.

Interpretive Guidelines § 483.362(c)

This assessment is conducted in person (i.e., face-to-face). Consistent with state law and facility policy, physicians or other licensed practitioners such as registered nurses, physician’s assistants or nurse practitioners may perform this assessment of the

resident's physical and psychological status if it is within the scope of their discipline and licensure.

§483.364 Monitoring of the resident in and immediately after seclusion.

***N0170
(Rev.)***

§483.364(a) Clinical staff, trained in the use of emergency safety interventions, must be physically present in or immediately outside the seclusion room, continually assessing, monitoring, and evaluating the physical and psychological well-being of the resident in seclusion. Video monitoring does not meet this requirement.

Interpretive Guidelines § 483.364(a)

“Physically present” should be defined as being in close enough proximity to the resident at all times to be able to verify that the resident is in no acute distress from the restraint or seclusion. The staff must be able to assess, at any given moment, the resident’s respirations, hear and respond to resident calls for assistance and observe changes in resident behavior.

“Continually assessing” should be defined as observing, measuring and evaluating at all times and documentation every 5 minutes of the ongoing assessment of the behavior and physical status of the resident by the staff that are physically present throughout the duration of the restraint or seclusion.

***N0171
(Rev.)***

§483.364(b) A room used for seclusion must—

- (1) Allow staff full view of the resident in all areas of the room; and***

Interpretive Guidelines § 483.364(b)(1)

Any area utilized as a seclusion room must be designed to enable the staff to be physically present, continually monitor and visualize the entire body of the resident in the seclusion room. Video monitoring may be used in addition to this room configuration but cannot be used in lieu of physical monitoring.

***N0172
(Rev.)***

§483.364(b)(2) Be free of potentially hazardous conditions such as unprotected light fixtures and electrical outlets.

Interpretive Guidelines § 483.364(b)(2)

Unprotected lights fixtures and electrical outlets are only two examples of potentially hazardous conditions and are not all-inclusive.

**N0173
(Rev.)**

§483.364 (c) If the emergency safety situation continues beyond the time limit of the order for the use of seclusion, a registered nurse or other licensed staff, such as a licensed practical nurse, must immediately contact the ordering physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion to receive further instructions.

Interpretive Guidelines § 483.364(c)

If necessary, prior to the expiration of the original order for restraint, a registered nurse or other licensed staff may telephone the physician or other licensed practitioner, report the results of his/her most recent assessment and obtain further instruction. If the practitioner advises that the ESI continue past the limits of the current order, the expectation is that a new order must be obtained, based upon current behaviors.

There must be documentation in the resident record of the behaviors which justified a new order for restraint.

**N0174
(Rev.)**

§483.364(d) A physician, or other licensed practitioner permitted by the state and the facility to evaluate the resident's well-being and trained in the use of emergency safety interventions, must evaluate the resident's well-being immediately after the resident is removed from seclusion.

Interpretive Guidelines § 483.364(d)

This assessment is conducted in person (i.e., face-to-face). Consistent with state law, physicians or other licensed practitioners such as registered nurses, physician's assistants or nurse practitioners may perform this assessment of the resident's physical and psychological status.

***§483.366 Notification of parent(s) or legal guardian(s).
If the resident is a minor as defined in this subpart:***

N0178

(Rev.)

§483.366(a) The facility must notify the parent(s) or legal guardian(s) of the resident who has been restrained or placed in seclusion as soon as possible after the initiation of each emergency safety intervention.

Interpretive Guidelines § 483.366(a)

Upon admission, the facility should obtain emergency contact information from the parent(s) or legal guardian(s). In the event that a parent or legal guardian cannot be contacted, the facility should have alternate methods for contacting parent(s) or legal guardian(s). Determine if the facility has a system of updating resident's contact information for each new admission or for residents who have been admitted for long periods of time.

The facility's policy should specify what information must be relayed to the parent or legal guardian regarding the initiation of restraint and seclusion.

"As soon as possible" is generally considered to be from the time of initiation of restraint or seclusion. Although a parent or guardian may request that they not be disturbed during certain periods of time during the day or night, the facility must still notify them but may delay notification to be consistent with their written instructions.

N0179

(Rev.)

§483.366(b) The facility must document in the resident's record that the parent(s) or legal guardian(s) has been notified of the emergency safety intervention, including the date and time of notification and the name of the staff person providing the notification.

Interpretive Guidelines § 483.366(b)

If the facility is unable to reach the parent or guardian at the time the restraint or seclusion is initiated, they must continue to try to reach them. The goal should be to communicate with a live person. However, a message will meet the notification standard after the second attempt.

§483.368 Application of time out

N0183

(Rev.)

§483.368(a) A resident in time out must never be physically prevented from leaving the time out area.

Interpretive Guidelines § 483.368(a)

Time out, as defined in this subpart, 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. Staff physically preventing the resident from leaving the time out area would be considered seclusion.

The definitions we have employed for “mechanical restraint” and “personal restraint” are modeled on the hospital definition of “restraint” codified in § 482.13(e)(1)(i). In this rule, we distinguish between “personal” and “mechanical” restraint to clarify that mechanical restraint means any device attached or adjacent to a person’s body, while personal restraint means the application of physical force on a person’s body without the use of any device.

N0184
(Rev.)

§483.368(b) Time out may take place away from the area of activity or from other residents, such as in the resident's room (exclusionary), or in the area of activity of other residents (inclusionary).

Interpretive Guidelines § 483.368(b)

Exclusionary time out is defined as the state of being excluded from participation by removal from the environment where an activity or group of individuals is located. Inclusionary time out is defined as a state of being included in the environment where an activity or group of individuals is located, but not participating in the activity or with the group. In either situation whether it be exclusionary or inclusionary, a resident cannot at any time be prevented from leaving the time out area.

N0185
(Rev.)

§483.368(c) Staff must monitor the resident while he or she is in time out.

Interpretive Guidelines § 483.368(c)

In those instances during efforts to use less restrictive measures where the staff requests that the resident take a time out, the staff must monitor the resident throughout the time out episode. Documentation should include time of initiation, progression of behaviors during the time out episode, time of ending time out and the resident’s disposition at the end of time out.

§483.370 Post intervention debriefings.

N0188
(Rev.)

§483.370(a) Within 24 hours after the use of the restraint or seclusion, staff involved in an emergency safety intervention and the resident must have a face-to-face discussion. This discussion must include all staff involved in the intervention except when the presence of a particular staff person may jeopardize the wellbeing of the resident. Other staff and the resident's parent(s) or legal guardian(s) may participate in the discussion when it is deemed appropriate by the facility. The facility must conduct such discussion in a language that is understood by the resident and by the resident's parent(s) or legal guardian(s). The discussion must provide both the resident and staff the opportunity to discuss the circumstances resulting in the use of restraint or seclusion and strategies to be used by the staff, the resident, or others that could prevent the future use of restraint or seclusion.

Interpretive Guidelines § 483.370(a)

The purpose of the debriefing is to provide both the resident and the staff an opportunity to analyze the events surrounding the emergency safety situation and intervention. It is essential that facilities include all four factors of §§483.370 (b)(1)-(4) in their debriefing, as well as review the emergency safety situation and intervention, in order to improve the resident's treatment plan.

Review of sample resident records to verify that the documentation of both the resident debriefing and the staff debriefing include:

- a. That a face to face debriefing was held within 24 hours of the conclusion of the restraint or seclusion episode;*
- b. Appropriate staff (and their names) were involved in the face to face debriefing (if one or more of the staff involved in the restraint or seclusion does not attend the face to face, there must be documentation to justify their absence);*
- c. That the resident was present for the debriefing;*
- d. If the resident is a minor, the parents or legal guardians were notified and given an opportunity to participate in the debriefing;*
- e. The meeting discussion includes documentation of how an restraint or seclusion may be prevented in the future based upon information learned from the episode; and*
- f. Any changes to the resident's treatment plan as a result of each debriefing.*

N0189
(Rev.)

§483.370(b) Within 24 hours after the use of restraint or seclusion, all staff involved in the emergency safety intervention, and appropriate supervisory and administrative staff, must conduct a debriefing session that includes, at a minimum, a review and discussion of –

§483.370(b)(1) The emergency safety situation that required the intervention, including discussion of the precipitating factors that led up to the intervention;

Interpretive Guidelines § 483.370(b)(1)

See Interpretive Guidance for § 483.370(a)

N0190

(Rev.)

§483.370(b)(2) *Alternative techniques that might have prevented the use of the restraint or seclusion;*

Interpretive Guidelines § 483.370(b)(2)

See Interpretive Guidance for § 483.370(a)

N0191

(Rev.)

§483.370(b)(3) *The procedures, if any, that staff are to implement to prevent any recurrence of the use of restraint or seclusion; and*

Interpretive Guidelines § 483.370(b)(3)

See Interpretive Guidance for § 483.370(a)

N0192

(Rev.)

§483.370(b)(4) *The outcome of the intervention, including any injuries that may have resulted from the use of restraint or seclusion.*

Interpretive Guidelines § 483.370(b)(4)

See Interpretive Guidance for § 483.370(a)

N0193

(Rev.)

§483.370(c) *Staff must document in the resident's record that both debriefing sessions took place and must include in that documentation:*

The names of staff who were present for the debriefing,

The names of staff who were excused from the debriefing, and

Any changes to the resident's treatment plan that result from the debriefings.

Interpretive Guidelines § 483.370(c)

See Interpretive Guidance for § 483.370(a)

§483.372 Medical Treatment for injuries resulting from an emergency safety intervention.

***N0196
(Rev.)***

§483.372(a) Staff must immediately obtain medical treatment from qualified medical personnel for a resident injured as a result of an emergency safety intervention.

Interpretive Guidelines § 483.372(a)

It is the responsibility of the facility to adequately assess the resident to determine the extent of any injuries sustained during an ESI and provide/secure the appropriate medical care promptly. Staff that is medically trained to provide emergency care and CPR should be available onsite, to provide the emergency medical interventions until further follow up emergency care can be provided.

***N0197
(Rev.)***

§483.372(b) The psychiatric residential treatment facility must have affiliations or written transfer agreements in effect with one or more hospitals approved for participation under the Medicaid program that reasonably ensure that—

Interpretive Guidelines § 483.372(b)

The facility must have written arrangements with one or more hospitals to receive residents in the case of an emergency.

***N0198
(Rev.)***

§483.372(b)(1) A resident will be transferred from the facility to a hospital and admitted in a timely manner when a transfer is medically necessary for medical care or acute psychiatric care;

Interpretive Guidelines § 483.372(b)(1)

If a resident is deemed to need medical care or acute psychiatric care, it is the responsibility of the facility to assure a timely transfer based on the urgent or emergent nature of symptom or injury presentation.

***N0199
(Rev.)***

§483.372(b)(2) Medical and other information needed for care of the resident in light of such a transfer, will be exchanged between the institutions in accordance with State medical privacy law, including any information needed to determine whether the appropriate care can be provided in a less restrictive setting; and

Interpretive Guidelines § 483.372(b)(2)

- 1. Review the facility policy to ensure it includes what information is required to be provided to the hospital upon resident transfer;*
- 2. Ensure that exchange of information per the facility policy is consistent with state law;*
- 3. Agreements between the PRTF and hospitals should include the required information that should be shared between the two entities; and*
- 4. Interview licensed staff to ensure they are familiar with and understand the policy regarding exchange of information with hospitals.*

N0200

(Rev.)

§483.372(b)(3) Services are available to each resident 24 hours a day, 7 days a week.

Interpretive Guidelines § 483.372(b)(3)

Written agreements or Memoranda of Understanding between the PRTF and hospitals must state that care will be available 24 hours a day, 7 days a week, including emergent care.

N0201

(Rev.)

§483.372(c) Staff must document in the resident's record, all injuries that occur as a result of an emergency safety intervention, including injuries to staff resulting from that intervention.

Interpretive Guidelines § 483.372(c)

The facility should have written policies and procedures that list all the elements that must be included in the documentation of any injury occurring during an ESI. Complete documentation of resident injuries must be included in the resident record.

Documentation of staff injuries resulting from emergency safety intervention must be referenced in the associated resident record. However, more detailed information concerning the staff injury may be located somewhere other than the resident record.

N0202

(Rev.)

§483.372(d) Staff involved in an emergency safety intervention that results in an injury to a resident or staff must meet with supervisory staff and evaluate the circumstances that caused the injury and develop a plan to prevent future injuries.

Interpretive Guidelines § 483.372(d)

This discussion may be included in the staff debriefing or may be documented separately. Documentation must address any staff procedures that will be changed as a result of the injury or what additional staff training will be required. Refer to N-0189, N-0190, N-0191, N-0192.

§483.374 Facility reporting

N0205

(Rev.)

§483.374(a) Attestation of facility compliance.

Each psychiatric residential treatment facility that provides inpatient psychiatric services to individuals under age 21 must attest, in writing, that the facility is in compliance with CMS' standards governing the use of restraint and seclusion. This attestation must be signed by the facility director.

Interpretive Guidelines § 483.374(a)

The State Survey Agency should have a copy of the current facility attestation on file. The surveyor should ensure that there is a current attestation on file for the facility prior to going on site. The surveyor should also verify through the State Medicaid Agency that the facility is still operational prior to going onsite.

N0206

(Rev.)

§483.374(a)(1) A facility with a current provider agreement with the Medicaid agency must provide its attestation to the State Medicaid agency by July 21, 2001.

(2) A facility enrolling as a Medicaid provider must meet this requirement at the time it executes a provider agreement with the Medicaid agency.

Interpretive Guidelines § 483.374(a)(1)-(2)

The attestation should include as a minimum:

- 1. The facility name and location;*
- 2. Total number of facility beds;*
- 3. Number of Medicaid residents in the facility;*
- 4. Number of residents for whom the Psych Under 21 is paid for by another state;*

5. A list of all states from whom the facility has ever received Medicaid payment for the provision of the Psych Under 21 benefit;
6. A statement certifying that the facility currently meets all of the requirements of Part 483, Subpart G governing the use of restraint and seclusion;
7. A statement that the facility will submit a new attestation of compliance in the event that the facility director is no longer in such position;
8. Name of individual and position of individual signing the attestation; and
9. The date the attestation was signed.

N0207
(Rev.)

§483.374(b) Reporting of serious occurrences.

- **The facility must report each serious occurrence to both the State Medicaid agency and, unless prohibited by State law, the State designated Protection and Advocacy system. Serious occurrences that must be reported include a resident's death, a serious injury to a resident as defined in section §483.352 of this part, and a resident's suicide attempt.**

(1) Staff must report any serious occurrence involving a resident to both the State Medicaid agency and the State designated Protection and Advocacy system by no later than close of business the next business day after a serious occurrence. The report must include the name of the resident involved in the serious occurrence, a description of the occurrence and the name, street address, and telephone number of the facility.

Interpretive Guidelines § 483.374(b)(1)

“Serious injury”, as defined in §483.352, 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. Serious injuries also include incidences of abuse and neglect.

All serious injuries that require medical intervention are to be reported, regardless of whether they were associated with the use of restraint or seclusion. It is the responsibility of the facility to ensure that it reports serious occurrences appropriately.

The facility need not report every injury that a resident experiences, but only those that are substantial in nature. For instance, a small bruise on a thigh, which occurred as a result of running into a table, or abrasions as a result of a fall, may not be appropriate to report. It is the expectation that a facility investigate any injuries of unknown origin to ensure that a resident is not being harmed. In addition, if a resident has repeated injuries that are indicative of a pattern the facility should investigate to ensure that the resident is not subjected to a hostile environment and take steps to minimize the risk of more injuries.

Deficiencies cited at 42 CFR 483.374 (b) involving a failure to report serious injuries resulting from abuse or neglect have greater probability of rising to an immediate jeopardy level finding. Immediate jeopardy procedures are outlined in Appendix Q of the State Operations Manual.

N0208
(Rev.)

§483.374(b)(2) *In the case of a minor, the facility must notify the resident’s parent(s) or legal guardian(s) as soon as possible, and in no case later than 24 hours after the serious occurrence.*

Interpretive Guidelines § 483.374(b)(2)

Review the facility policy to verify that:

- a. The policy requires parental/legal guardian notification within 24 hours after a serious occurrence; and*
- b. That the policy specifies who should notify the parent/legal guardian.*

Review a sample of the serious occurrence reports. Verify that notification to parents or guardians was timely, within 24 hours.

Survey procedures and probes

- 1. Review policy to determine:*
 - That the policy requires parental/ legal guardian notification within 24 hours after a serious occurrence.*
 - That the policy specifies who should notify the parent/ legal guardian and what information should be given.*
 - Documentation of notification is recorded in the resident’s chart.*
- 2. Review documentation of serious occurrences to determine if notification to parents or guardians was timely, within 24 hours.*

N0209
(Rev.)

§483.374(b)(3) *Staff must document in the resident’s record that the serious occurrence was reported to both the State Medicaid agency and the State designated Protection and Advocacy system, including the name of the person to whom the incident was reported. A copy of the report must be maintained in the resident’s record, as well as in the incident and accident report logs kept by the facility.*

Interpretive Guidelines § 483.374(b)(3)

Review the facility policies to determine:

- a. That “serious occurrence” is defined in a manner that is consistent with this regulation;*

- b. That the policies include procedures that staff must follow in reporting serious occurrences;*
 - c. If the facility designates who should report and follow up on serious occurrences;*
 - d. If the policy addresses investigation of injuries of unknown origins*
- Interview staff to determine what method the facility uses to report serious occurrences. Ensure that the staff is able to differentiate between what should and should not be reported.*

During the onsite survey, request a list of all the serious occurrences reported to the state Medicaid agency and the Protection and Advocacy organization within the past year. Observe for patterns of injury that may be associated with action or inaction on the part of the facility.

N0210
(Rev.)

§483.374(c) Reporting of deaths. In addition to the reporting requirements contained in paragraph (b) of this section, facilities must report the death of any resident to the Centers for Medicare and Medicaid Services (CMS) regional office.

(1) Staff must report the death of any resident to the CMS regional office by no later than close of business the next business day after the resident's death.

(2) Staff must document in the resident's record that the death was reported to the CMS regional office.

Interpretive Guidelines § 483.374(c)

Review the facility policies to determine:

- a. The policy requires notification to the CMS RO no later than COB of the next business day after residents death, and*
- b. The policy should specify who should notify the CMS RO.*

§483.376 Education and Training

N0214
(Rev.)

§483.376(a) The facility must require staff to have ongoing education, training, and demonstrated knowledge of –

Interpretive Guidelines § 483.376(a)

The facility staff must attend ongoing training and education activities in the required areas outlined below (N-0215-N-0218). It is imperative that the facility identify and

provide for the training needs of staff based upon their responsibilities to include direct care staff as well as administrative, clerical and housekeeping staff. Review the facility documentation in staff files to verify that the training is occurring.

N0215

(Rev.)

§483.376(a)(1) Techniques to identify staff and resident behaviors, events, and environmental factors that may trigger emergency safety situations;

Interpretive Guidelines § 483.376(a)(1)

The facility must provide educational and hands-on training to staff that assists them in identifying and understanding psychiatric behaviors exhibited by the residents. Educational training is intended to teach concepts and knowledge, such as in an explanation and discussion of various less restrictive interventions that may be used in a given situation. Hands-on training is taught through practical experience, such as watching how a restraint is applied and then applying what was learned through a return demonstration. This training should include the identification of staff roles and behaviors that affect negative outcomes and the assessment of the impact of the resident's environment contributing to an emergency safety situation.

N0216

(Rev.)

§483.376(a)(2) The use of nonphysical intervention skills, such as de-escalation, mediation conflict resolution, active listening, and verbal and observational methods, to prevent emergency safety situations; and

Interpretive Guidelines § 483.376(a)(2)

The facility must provide education and training in the areas of therapeutic, nonphysical intervention skills that will enable them to identify a potential emergency safety situation. Through early identification of such situations, staff can intervene to prevent a situation from escalating to the point where an emergency intervention is necessary. Training methods and skills such as de-escalation, mediation conflict resolution, active listening techniques, verbal and observational methods must be taught through educational and hands-on means.

The facility must also include training on the correct application of time out and how to monitor a resident in time out.

N0217

(Rev.)

§483.376(a)(3) The safe use of restraint and the safe use of seclusion, including the ability to recognize and respond to signs of physical distress in residents who are restrained or in seclusion.

Interpretive Guidelines § 483.376(a)(3)

The facility must provide training and education for all staff in the safe application and use of restraint techniques. This training should include the demonstrated safe application of any restraint devices utilized by the facility. Training in the techniques of the safe use of seclusion should include various methods available in assisting residents into seclusion rooms. Training should also include the identification of signs and symptoms of physiological and/or psychological distress in a resident during an ESI and staff responses to the identification of resident distress to include CPR, and removal of physical barriers impacting on the resident's safe care.

N0218

(Rev.)

§483.376(b) Certification in the use of cardiopulmonary resuscitation, including periodic recertification, is required.

Interpretive Guidelines § 483.376(b)

The facility must ensure that all staff that has direct resident care responsibilities receive certification training in the use of cardiopulmonary resuscitation (CPR) for all age categories as recommended by the guidelines from the American Heart Association. Continuing recertification requirements should be included in the facility training plans.

N0219

(Rev.)

§483.376(c) Individuals who are qualified by education, training and experience must provide staff training.

Interpretive Guidelines § 483.376(c)

The facility has the responsibility for assuring the credentials of their training staff. The staff trainers/instructors must be educated, trained and experienced in the areas of expertise in which they teach. Trained staff may be either employed by the facility in staff positions or services may be on a contractual basis. If the training services are provided under contractual agreements, review the procedure for evaluation of the services provided to the facility.

N0220

(Rev.)

§483.376(d) Staff training must include training exercises in which staff members successfully demonstrate in practice the techniques they have learned for managing emergency safety situations.

Interpretive Guidelines § 483.376(d)

As part of the staff training program for managing emergency safety situations, there must be experiential (hands-on) opportunities provided to the staff. Training scenarios should be included in training sessions and emphasize the important techniques taught and any remediation training provided. Trainer observations of these exercises must be documented.

***N0221
(Rev.)***

§483.376(e) Staff must be trained and demonstrate competency before participating in an emergency safety intervention.

Interpretive Guidelines § 483.376(e)

The facility policy must require that all staff must be trained and have documented evidence of demonstrated competency before they may participate in an emergency safety situation.

***N0222
(Rev.)***

§483.376(f) Staff must demonstrate their competencies as specified in paragraph (a) of this section on a semiannual basis and their competencies as specified in paragraph (b) of this section on an annual basis.

Interpretive Guidelines § 483.376(f)

- 1. Review a sample of staff personnel files to verify that staff has demonstrated their competence on a six month basis.*
- 2. Review a sample of personnel files to verify that staff is recertified in CPR on an annual basis.*

***N0223
(Rev.)***

§483.376(g) The facility must document in the staff personnel records that the training and demonstration of competency were successfully completed. Documentation must include the date training was completed and the name of persons certifying the completion of training.

Interpretive Guidelines § 483.376(g)

The facility must document all successfully completed competency evaluations in the personnel files or training records. This documentation should include the dates the training was completed and the names of the responsible staff that certified the completion of the competency evaluations.

N0224
(Rev.)

§483.376(h) All training programs and materials used by the facility must be available for review by CMS, the State Medicaid agency, and the State survey agency.

Interpretive Guidelines § 483.376(h)

The facility training documentation should be easily accessible and must be current.