DATE: December 11, 2003

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group


Letter Summary

This memo:
1) Outlines in general the responsibilities of all parties under the interim final rule governing the use of restraint and seclusion in Psychiatric Residential Treatment Facilities (PRTFs) providing inpatient psychiatric services for individuals under age 21;

2) Shares documents that will aid in the oversight and survey process of this newly established provider type, i.e., contact lists for Centers for Medicare & Medicaid Services (CMS) - Regional Office (RO), a Protection and Advocacy agency (P&A) contact list for each state, and a model attestation letter previously distributed in a State Medicaid Director’s Letter; and

3) Provides an interim final appendix to the State Operations Manual (SOM) for the survey process and interpretive guidelines for PRTFs. We expect the final appendix to be available in the summer of 2004.

I. Background
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. Both rules, the interim final and its amendment can be accessed on www.access.gpo.gov under the published dates of January 22, 2001, and May 22, 2001. The questions and answers on the interim final rule can be found on CMS’ website at www.cms.hhs.gov/Medicaid/services/psyrtf2.asp. The rule is codified and is located at 42 CFR Part 483 Subpart G §§ 483.350-483.376.
II. Responsibilities
This interim rule established validation, complaint and reporting requirements as well as annual attestation requirements. These responsibilities are described in brief in this document, however a more detailed discussion and outline of responsibilities is included in the interim final appendix to the SOM in attachment D.

**State Survey Agency (SA)**
- Conduct 20 percent yearly validation surveys (including complaint surveys due to the improper use of restraint and seclusion). The 20 percent will be pro-rated in FY 2004 according to the SOM publication date.

**State Medicaid Agency (SMA)**
- Share reported information with its State licensing agency (usually the SA) responsible for licensing health institutions within the State. (42 CFR 431.610 (e)(2)). All discussion related to SMAs was included and disseminated in SMDL #01-023, dated July 11, 2001.

**PRTFs**
- Report serious occurrences, which include deaths, serious injuries, and attempted suicides that may be due to the use of restraint or seclusion to the SMA and the State-designated P&A agency (see attachment B). Report to CMS RO any resident’s death (see attachment A).
- Document in the resident’s record that the death was reported to the CMS contact and document that any serious occurrence, including death, serious injury, or attempted suicides were reported to the SMA and the State-designated P&A agency.

**CMS**
- CMS-RO: Receive and maintain death report data for PRTFs and send death report data to Central Office’s Survey and Certification Group/Division of Continuing Care Providers.
- CMS-Central Office: maintain a central log of death report data as reported by the ROs.
- Develop and disseminate a survey protocol for validation and complaint investigation surveys, and conduct trainings for State and Federal surveyors.

III. Next Steps
We expect facilities to have implemented the interim final rule, including the attestation requirements as of July 21, 2001. CMS conducted satellite training on November 14, 2003 based on interim final requirements. The training can be accessed via our website at [http://cms.internetstreaming.com](http://cms.internetstreaming.com)

Additional training will be provided after publication of the final rule.

If you have any questions about this memorandum or guidance please contact Carla McGregor at 410-786-0663.
Effective Date: Immediately. We have attached a interim final appendix of the SOM for the survey process and interim guidelines for PRTFs because the rule is not yet final. The document will still require a formal CMS clearance process and will be issued in final form in the summer of 2004, at the time of the final rule publication. Any changes to the final rule will be reflected in the SOM and surveyor guidance.

Action Steps:
1) Survey agencies are expected to begin gathering information on PRTFs in their states.  
2) Survey agencies are to begin surveys in March 2004 or shortly thereafter upon the completion of data input system.

Termination: Facilities who fail to report a death or who are found out of compliance with the conditions of participation will be terminated from the Medicaid program.

Training: This information should be shared with all survey and certification staff, surveyors and their managers, the State and regional office training coordinators, and the designated mental health regional office contact person.

Thank you in advance for your partnership in accomplishing these endeavors.

/s/
Thomas E. Hamilton

Attachment A: CMS Regional & Central Office Contacts  
Attachment B: Protection & Advocacy State Office Contacts  
Attachment C: Model Attestation Letter  
Attachment D: Interim Final State Operations Manual: PRTF survey process and interpretive guidelines

cc:  
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Coalition Chair, Advocacy Coalition  
Senior Policy Counsel  
National Association of Protection and Advocacy Systems

State Medicaid Agency Directors  
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Siera Gollan
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<table>
<thead>
<tr>
<th>State Protection And Advocacy Agencies For Persons With Developmental Disabilities, Mental Illness And The Client Assistance Program</th>
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</table>
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Model Attestation Letter
(The facility director must sign this attestation.)

Name of the Psychiatric Residential Treatment Facility
Address
City, State, Zip Code
Telephone Number
Fax Number

State Provider Number
Federal Provider Number

Dear <State Medicaid Director>:

A reasonable review has been conducted in the subject facility. Based upon my best knowledge, information, belief, and reasonable interpretation and understanding of the requirements set forth in the interim final rule governing the use of restraint and seclusion in psychiatric residential treatment facilities providing inpatient psychiatric services to individuals under age 21 published on January 22, 2001, and amended with the publication of May 22, 2001, on behalf of <Name of the Facility>, I hereby attest that <Name of the Facility> complies with all of the requirements set out in that regulation as codified at 42 CFR §§ 483.350-483.3.76.

I understand that the Centers for Medicare & Medicaid Services (CMS), (formerly the Health Care and Financing Administration (HCFA)), the State Medicaid Agency or their representatives may survey <Name of the Facility> to determine compliance with the requirements set forth in the Condition of
Participation as established by the interim final rule in accordance with and to the extent authorized by 42 CFR § 431.610.

In addition, the <Name of the Facility> will notify the <Name of State Medicaid Agency> immediately if I vacate this position so that an attestation can be submitted by my successor.

Signature
Printed Name
Title (Facility Director)
Date

Attachment D

SURVEY PROCEDURES AND INTERPRETIVE GUIDELINES
FOR PSYCHIATRIC RESIDENTIAL TREATMENT FACILITIES

Part 1
BACKGROUND
I. Policy for Conducting Surveys
II. The Basis For The State Survey Agency Activities Under Title XVIII & XIX of The Social Security Act (“Act”)
III. Use of Survey Protocol in Survey Process
IV. Determination-Making Authority
   A. Medicaid Approval
   B. Authorization of Certification Expenditures
   C. Appeals
V. Psychiatric Residential Treatment Facilities (PRTFs)
   A. Historical Development of PRTFs
   B. Definitions and Citations
   C. Accreditation
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**Part 2**

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This appendix is created to address survey issues directly related to psychiatric residential treatment facilities (PRTFs). Psychiatric residential treatment facilities are newly identified Medicaid-only facilities and thus, until the publication of an interim final rule in January 2001, have not been required to meet Federal conditions of participation. The intent of this appendix is to provide the State Survey Agency (SA) with instructions on pertinent aspects of the surveying process for PRTFs, in addition, this appendix mirrors many aspects of the survey process already established in Chapter Two, sections 2700 through 2736. Those aspects discussed in length in Chapter Two are only provided as general summation in this appendix and thus surveyors should refer back to these relevant and comparable sections in Chapter Two. In addition, if a situation arises that has not been addressed in this appendix please refer back to Chapter Two for guidance. If additional direction is required, contact the CMS Regional Office (CMS-RO).

BACKGROUND

I. POLICY FOR CONDUCTING SURVEYS
The Centers for Medicare & Medicaid Services’ (CMS) has in place an outcome-oriented survey process for all certified providers. Surveys of psychiatric residential treatment facilities will be no different. The focus of an outcome-oriented survey is to determine whether the facility is actually providing services rather than whether the facility is capable of providing them. The Social Security Act mandates the establishment of minimum health and safety standards, which must be met by providers and suppliers participating in the Medicare and Medicaid programs. The following information provided in this appendix is geared to achieve this goal.

II. THE BASIS FOR THE STATE SURVEY AGENCY ACTIVITIES UNDER TITLE XVIII & XIX OF THE SOCIAL SECURITY ACT (“ACT”)
Section 1864(a) of the Act directs the Secretary to use the State health agencies or “other appropriate agencies” to determine whether health care institutions meet standards. This function is termed provider certification.

Section 1902(a)(9)(A) requires that a State use the same agency to establish and maintain additional standards for the State Medicaid program. Section 1902(a)(33)(B) requires that the State agency licensing health institutions (in effect, the same agency) also determine whether institutions meet all applicable Federal health standards for Medicaid participation, subject to validation by the Secretary of Health and Human Services.

III. USE OF SURVEY PROTOCOL IN THE SURVEY PROCESS
Survey protocols are established to provide surveyors with guidance in conducting surveys to assess the compliance of providers and suppliers participating in the Medicare and Medicaid programs with certain regulatory requirements. Survey protocols appear in the various appendices to this manual, the State Operations Manual (SOM). The purpose of this protocol is to provide instructions, check lists, and other tools for use in preparing for the survey, conducting the survey, and post survey activities. Survey protocols are to be used by all surveyors to measure compliance with Federal requirements. They are authorized interpretations of mandatory requirements set forth in the provisions of the Act and the regulations.
IV. DETERMINATION –MAKING AUTHORITY

A. MEDICAID APPROVAL

Medicaid law requires that the same State Survey Agency 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 State agency responsible for the overall management of the Medicaid program. Therefore, in each State, a State Medicaid agency is ultimately responsible for Medicaid program administration. Each State Medicaid agency enters into an interagency agreement with its certifying SA establishing the determination-making function of the certifying SA and providing for the application of Federal certification standards and procedures. The State Medicaid agency must accept the SA’s certification decisions as final, but exercise its own determination whether to enter into agreements with approved skilled nursing facilities (SNFs), intermediate care facilities (ICFs), including intermediate care facilities for persons with mental retardation (ICFs/MR), and psychiatric residential treatment facilities (PRTFs). The State Medicaid agency is responsible for reviewing certifications to ensure that the SA had adhered to procedural requirements. If the State Medicaid agency disagrees with the SA’s certification, it first contacts the SA to resolve the issue. If the issue cannot be resolved, the State Medicaid agency contacts the CMS-RO. (See also discussion in State Medicaid Manual (SMM)).

B. AUTHORIZATION OF CERTIFICATION EXPENDITURES.

Authority to approve Medicare certification budgets and expenditures is delegated to the CMS Regional Administrators. Authority to approve or disapprove FFP in Medicaid certification expenses is also delegated to the CMS Associate Regional Administrators.

C. 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. When a facility participates in both the Medicare and Medicaid programs, any Medicare adverse action also applies to Medicaid, including the Medicare appeals procedures. 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. A facility has no right to an appeal in cases where CMS disallows FFP on the grounds that the State agency has improperly certified the facility.

V. PSYCHIATRIC RESIDENTIAL TREATMENT FACILITIES (PRTFs)

A. HISTORICAL DEVELOPMENT OF PRTFs

The Social Security Amendments of 1972 amended the Medicaid Statute to, among other things, allow States the option of covering inpatient psychiatric hospital services for individuals under age 21 (Psych under 21 benefit). Originally the statute required that the psych under 21-benefit be provided by psychiatric hospitals that were accredited by, what is now called the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

In 1976 final regulations were published implementing the psych under 21-benefit. These regulations allowed the coverage of this benefit in psychiatric facilities that were accredited by JCAHO. In 1981 CMS received comments from the JCAHO expressing concern about CMS’s regulatory requirement for JCAHO accreditation. The JCAHO indicated that this Federal requirement was in conflict with JCAHO’s policy that facilities should seek accreditation voluntarily. In response, CMS noted that the regulatory requirement for JCAHO accreditation could not be removed because it was required by statute.
In 1984, the Congress amended section 1905(h) of the Act, removing the requirement for JCAHO accreditation and adding the requirement that providers of the psych under 21 benefit meet the definition of a psychiatric hospital under the Medicare program as specified in section 1861(f) of the Act. Despite this statutory change, based on CMS understanding of Congressional intent, CMS did not remove the requirement for JCAHO accreditation from CMS regulations, which are in subpart D of 42 CFR part 441. CMS’ reliance on JCAHO accreditation was the only basis for coverage of the psych under 21-benefit in psychiatric facilities other than psychiatric hospitals. CMS’ decision to retain the regulatory requirement for JCAHO accreditation was based on the fact, in enacting the 1984 amendment, the Congress gave no indication that it intended to narrow the psych under 21 benefit or alter CMS policy that had been in effect since 1976.

In 1990, the Omnibus Budget Reconciliation Act of 1990 (OBRA ’90) was enacted and consistent with CMS’ interpretation reflected in 42 CFR 441 et seq., section 4755 of OBRA ’90 amended section 1905(h) of the Act to specify that the psych under 21 benefit can be provided in psychiatric hospitals that meet the definition of that term in section 1861(f) of the Act “or in another inpatient setting that the Secretary has specified in regulations.” This amendment affirmed and effectively ratified preexisting CMS policy as articulated in subpart D of 42 CFR part 441, which interpreted sections 1905(a)(16) and 1905(h) of the Act as not being limited solely to psychiatric hospital settings. OBRA ’90, therefore, provides authority for CMS to specify inpatient settings in addition to the psychiatric hospital setting for the psych under 21-benefit without continuing to require that providers obtain JCAHO accreditation. Thus, CMS established the PRTF as a separate type of inpatient setting.

B. DEFINITIONS AND CITATIONS

Psychiatric Residential Treatment Facility. —A psychiatric residential treatment facility is defined in 42 CFR § 483.352. A PRTF is a facility other than a hospital, that provides psychiatric services, as described in subpart D of part 441 of this chapter [iv], to individuals under age 21, in an inpatient setting. Section 441.151, in subpart D indicates that these are to be accredited by either the JCAHO, 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. Psychiatric residential treatment facilities, as indicated in § 483.374 must also have either a current provider agreement with the Medicaid agency or if enrolling as a Medicaid provider must execute a provider agreement with the Medicaid agency.

Psychiatric Services for Individuals Under age 21 Benefit. --The psych under 21 benefit, at section 1905(a)(16) of the Act, is optional. The psych under 21 benefit must, however, 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.

Conditions of Participation for the Use of Restraint and Seclusion. —Established in 42 CFR Part 483, subpart G are the Conditions of Participation (CoPs) that PRTF’s are to adhere to in order to participate in the Medicaid program. It is currently the only CoP established for PRTFs. The
CoPs are separated into twelve sections and each section is covered in detail within the interpretive guidelines found in Part Two of this appendix. The CoPs cover the following areas:

- 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
- Postintervention debriefing
- Medical treatment for injuries resulting from an emergency safety intervention
- Facility reporting requirements
- Facility’s responsibility in educating and training its staff

C. ACCREDITATION

The accreditation organizations for PRTFs are approved according to State based standards. JCAHO, COA, and CARF are all nationally recognized accrediting organizations. JCAHO and CARF provide accrediting services directly to the providers. The Council on Accreditation accredits State-level organizations and evaluates the organizations ability to provide services for families and children. This accreditation process is not considered to have similar deeming authority as authorized by the Act in the case of hospitals or other such providers. The accreditation process for PRTFs has been based on requirements as set forth in 42 CFR §§ 441.151 through 441.156. Since a new Condition of Participation has been created, the SAs are now responsible for surveying and validating whether PRTFs are meeting the Federal requirements set forth in part 483 subpart G.

D. LOOK-BEHIND AUTHORITY.

CMS has the authority to “look behind” State determinations and, with cause, to make binding determinations (section 1902 (a)(33)(B)). CMS has two kinds of look behind authority. Only one of these look behind authorities apply in the case of psychiatric residential treatment facilities. An example of this 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 State Medicaid agency may have issued the provider agreement even though the SA certified the facility as not being in compliance. In that case, the agreement is void from its inception. The State would not be entitled to FFP related to that facility. CMS may conduct a look behind survey under other reasons as well, in addition to the example provided. This authority is established by 42 CFR 442.30. (See discussion of “new” look behind authority in SMM §2084.3, SOM §3005 G for ICFs/MR, “old” look behind authority involves SNFs, NFs and formerly ICF/MR, and SOM §3042).

E. SURVEY AGENCY RESPONSIBILITIES & OBLIGATIONS

Attestations

- PRTFs are to send attestations to each State Medicaid Agency where they have established a provider agreement.
- Attestations are to be sent 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.
States where the PRTF resides inputs the initial attestation information into OSCAR and continually thereafter if the SA is in fact responsible for validation and complaint surveying.

Attestations are to include the following information:

- Facility General Characteristics: name, address, telephone number of the facility, and a State provider identification number;
- Facility Specific Characteristics: (a) bed size, (b) 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), (c) number of individuals, if any, whose Medicaid Psych under 21 benefit is paid for by any State other than the State of the PRTF identified in this attestation letter, (d) identify by 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 State Survey Agency (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.

**Oscar Reports**

- Initial input of information from attestation – must be done by PRTF’s state of residence, even if the State in which the PRTF resides does not include the Psych under 21 benefit in its State plan.
- Maintaining attestation and survey information is the responsibility of the SA, that is conducting complaint and validation surveys.
- The entry of data into the Online Data Input and Edit (ODIE) subsystem of the Online Survey Certification and Reporting System (OSCAR) (SOM §4149) will be the responsibility of the SA. After the SMA assigns a Provider Identification Number to the PRTF, the SA is to enter information received from the PRTFs’ annual attestation as well as information from validation or complaint surveys. It is also the responsibility of the SA to update information on an as needed basis. The SA is to input information from Forms CMS- 1539, CMS- 670, CMS-2567 and if applicable, CMS-2567B, which are described below.

**Provider Identification Numbers**

- PRTFs are assigned providers numbers by the State Medicaid Agency.
- A provider number is coded based on where the PRTF is physically located.
- Processing of requests for payment is usually keyed to the Federal identification number, however the effect this identification number has on PRTFs is for OSCAR tracking purposes only.
Assigning Provider Identification Numbers.-- The State Medicaid Agency is responsible for designating a Federal provider identification number. The identification numbers for PRTFs will have five digits and one letter. The first two digits identify the State in which the psychiatric residential treatment 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. 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, if for example it was the fourth PRTF identified by the State, the PRTF’s Federal identification number would be 21L004.

Multi-State Issues: Survey and Validation responsibilities.

With the establishment of PRTFs as a Medicaid provider and because the psych under 21 benefit is an optional benefit, a number of State-to-State differences may occur. A State will either have the psych under 21-benefit in its State plan or it will not. However, not all States will have a facility within its borders that can meet the service needs of its Medicaid beneficiaries and thus will have to transfer its beneficiary to another State to receive the needed service.

If a State has the benefit in its State plan and it has an accredited PRTF within its State borders, then the SA where the PRTF resides is responsible for conducting complaint and validation surveys as part of its 20 percent obligation. The SMA is responsible for enforcement action if the PRTF is found out of compliance with the Condition of Participation.

In the few States where the benefit is not in the State plan, there may be PRTFs in that State that other States are sending beneficiaries, in this case it is the responsibility of all affected States to develop a method of communication and agreement amongst themselves as to which SA will survey a given PRTF. In Section 4.11 of the State Plan, relations with standard-setting and survey agencies, the State Medicaid Agency should identify which entity is responsible for conducting the validation and/or complaint surveys of PRTFs. PRTFs are only obligated to conform to its own State licensing laws.

Action for Non-Compliance and Termination.--Psychiatric Residential Treatment Facilities are Medicaid-only facilities. The SMA takes action against the PRTF, if the SA determines the PRTF is not in compliance. If a PRTF is found to be out of compliance with the condition of participation and fails to report a death then the PRTF is to be terminated from the Medicaid program. If there are conflicting determinations between the SA and the SMA, the CMS-RO’s role is to settle these conflicts.

THE SURVEY PROCESS

I. PRE-SURVEY PROCEDURES
   A. ANNOUNCED AND/OR UNANNOUNCED SURVEYS
It is CMS policy to have unannounced surveys for all providers and suppliers. While the unannounced surveys may result in some minor survey problems, this policy represents changing public attitudes and expectations toward compliance surveys. If there is any conflict with internal State policies and practices, the SA should discuss the problem with its SMA. Exceptions include some non-long term care facilities, which may be given advance notice, usually no more than 2 working days before an impending survey. These exceptions are identified and discussed within Chapter Two, §2700 of the SOM. Since all residents of a PRTF
will be represented by either, a parent or legal guardian, consent will be required prior to a resident being interviewed. Announcing a validation survey for a PRTF of over 16 beds, with no more than 2 working day advance notice, may fall within an exception to an unannounced survey. However if an individual notifies a provider of an unannounced survey, that individual is subject to Civil Money Penalties (CMPs) as established in sections 1819(g)(2)(A)(I), 1919 (g)(2)(A)(I), and 1891 (c)(1) of the Social Security Act.

B. SURVEY FREQUENCY
1. Introduction - The State Medicaid Agency must report all serious occurrences, as defined in 42 CFR 483.374(b) to its survey agency and the survey agency must conduct both validation and complaint surveys based on regulations established within 42 CFR 483 subpart G and further discussed within the interpretive guidelines as established in this appendix in Part 2. The survey agency will be advised annually in the budget call letter on the expected validation requirements for its State’s psychiatric residential treatment facilities.

2. Scheduling and Conducting Surveys---If an immediate jeopardy has been alleged, the State survey agency must investigate, on site, within 2 working days of the complaint receipt. For non-immediate jeopardy situations, the SMA with the SA should establish a mechanism by which to prioritize the nature of complaints.

3. Frequency---The State may conduct surveys as frequently as necessary to determine the facility’s compliance with the participation requirements and to also determine if the facility has corrected any previously cited deficiencies.

C. SURVEY TYPES
Validation Surveys.--- We expect States to validate the attestations for a sample of the facilities on an annual basis. Validation requires that the SA review attestation letters, conduct on-site review of PRTF based on criteria established in 42 CFR 441.151 through 441.156, and determine compliance with Federal standards as set forth in 42 CFR 483, subpart G and further discussed in the interpretive guidelines that follow in Part 2. The SAs are required to conduct 20% validation surveys and thus all PRTFs within a State should be surveyed within a 5-year period.

Complaint Surveys.---
1. Immediate Jeopardy --- The SA investigates on site, all allegations of immediate jeopardy 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. Look to appendix Q for complete guidance on immediate jeopardy. To determine if an immediate jeopardy situation is present and on-going an assessment of each complaint intake must be made by an individual who is professionally qualified to evaluate the nature of the problem based upon his/her knowledge of current clinical standards of practice and Federal requirements.

An “investigation,” in an alleged immediate jeopardy situation, is a review, conducted on site, to determine if a deficient practice is or was present, and to assess the degree of harm to any resident.
Exception – If the SA receives a restraint/seclusion death report, the SA must complete the investigation within 5 working days of report receipt.

2. Non-immediate jeopardy --- For non-immediate jeopardy situations, the SMA with the SA should establish a mechanism by which to prioritize the nature of complaints. The SA should assess facility compliance with the established regulations in 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 SA. Since, the SMA makes the initial determination for an enforcement action, the SA should then notify the SMA that a complaint was received and an investigation is underway.

In addition, we propose that the following procedures already established in CMS’s State Operations Manual (SOM) serve as a basis for direction for the SA and should follow the time line schedule as established in the sections below.

- 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 ICFs/MR (Not Applicable to Federal Termination of Medicaid Facilities) – Up until the creation of PRTFs as a provider, NFs and ICFs/MR served as the only two types of identified Medicaid-Only Facilities, for which CMS established Conditions of Participation. This SOM section identifies “denials, terminations, cancellations, and denials of payment for new admissions and other adverse actions to facilities participating in Medicaid-only are State administrative actions and decisions.” Thus we propose this as a guide for States.
- SOM §§3280-3283: 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…”

D. PREPARATION
The SA in preparation for the survey, reviews all necessary documents including attestation letter, licensure or accreditation records, and previous survey reports including complaints. This prior review will prove beneficial in determining composition of survey team and the time required for the validation or complaint survey. The SA schedules the survey in a manner that results in the most efficient and effective utilization of survey staff and that provides the most comprehensive look at the facility. Other considerations also include efficient and effective utilization of facility staff time as well. For additional guidance on pre-survey preparation, survey team workload and survey team composition; refer back to §§2704-2706 in Chapter Two.

II. ON-SITE SURVEY PROCEDURES
A. ENTRANCE INTERVIEW
The entrance interview sets the tone for the entire survey. Be prepared, courteous, and make requests, not demands. Upon arrival, the surveyor 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, the time schedule, and explains the process.

Inform the PRTF that the survey will include a tour of the facility, record reviews, observations, and interviews with residents, families/guardians, and personnel involved. Establish personnel availability and discuss approximate time frames for survey completion. Explain that an exit conference may be held to discuss survey findings. Identify who will be available of the facility staff, to direct questions as they arise. Refer to general discussion below and SOM § 2724 for additional information regarding exit conferences.

Request that the PRTF collect any documents, records, or information that may be needed to complete the survey, and solicit and answer any questions the PRTF may have concerning the survey process.

During the entrance interview surveyors should request a listing of all residents at the facility, including their age or date of birth, who in the past calendar year, from the time of the survey:

1. Have been secluded or restrained.
2. Have been injured.
3. 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.
4. Has a communication barrier, such as children who speak a foreign language.
5. Has been transferred to or from a hospital.
6. Are deceased.

Any information shared or received is to be kept in strict confidence.

Survey Team Composition – Survey team size and composition vary according to the type of provider/supplier and the purpose of the survey. Professional disciplines and experience represented by the survey team is to reflect the expertise needed to determine compliance with the CoP. Also the SA should consider special characteristics of the provider in selecting members of the survey team. In all instances, members of the survey team must meet education and training qualifications specified in §4009.

In general, the size of teams is governed by the size and type of the provider. PRTF survey teams are to include personnel with expertise in child psychiatry and/or with expertise in developmental disabilities, and all members are to survey together during the same time intervals.

B. INFORMATION GATHERING

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 reflect a proportionate representation of all residents who have been restrained or secluded. 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 actual experience and observation while on-site at the facility.
Conduct the interviews and observation of the resident within the context of the environment in which the resident lives, receives treatment and spends major leisure time. Although focus should be on the sampled resident, the behavior and interactions of all other residents and staff within those environments also contributes to the total context.

As the sample is built, 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 review. Documentation must include the reasons for adding residents to the sample. Residents may also be added to the sample as dictated by individual needs or problems. When the surveyor is on-site, if a resident is restrained or secluded during the survey, that resident should be added to the sample. Substitute residents in the sample only if it would be harmful and/or counter-therapeutic, as determined by facility staff, to include the originally selected resident. An example may be a resident with acute paranoid schizophrenia, who may become agitated if interviewed and observed. Any substitutions must be subject to change as needed.

Sample Size - Calculate the size of the sample by the following guidance:

<table>
<thead>
<tr>
<th>Number of Residents (restrained/secluded) residing in the Facility</th>
<th>Number of Residents in the sample</th>
<th>Number of Interviews with Residents</th>
</tr>
</thead>
<tbody>
<tr>
<td>4 - 8</td>
<td>50 percent</td>
<td>50 percent of sample</td>
</tr>
<tr>
<td>9 - 16</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>17 - 50</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>51 - 100</td>
<td>10</td>
<td>5</td>
</tr>
<tr>
<td>101 - 500</td>
<td>10 percent</td>
<td>50 percent of sample (max: 15)</td>
</tr>
<tr>
<td>Over 500</td>
<td>50</td>
<td>15</td>
</tr>
</tbody>
</table>

Sample Selection - Do not allow the facility to select the sample.

Draw the sample randomly from the list provided by the facility before beginning the survey to ensure that the sample is not unduly influenced once the survey begins. Choose names randomly from that list. If possible, ensure that at least one resident from the above criteria is represented in the sample. The sample should represent the various age ranges of residents who reside in the facility. The three main age groups that have impact on seclusion and restraint policy and practice are the ages 18 to 21; 9 to 17 and under age 9 years.

Audit Approach. To maximize the advantage of an interdisciplinary survey team, the 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 knowledge and competencies.

Documentation – Document the sample in form CMS-807 Surveyor Notes Worksheet -The team leader is to 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 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. At a minimum, identify, at the time of the survey:
   • 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.
   • The number, if any, of the residents substituted in the sample, including the reason for withdrawing the original resident record.

TASK 2 - RECORD REVIEW OF INDIVIDUALS IN THE SAMPLE

Introduction—Review all aspects of each resident's record to determine compliance with the condition of participation (CoP) for the use of restraint or seclusion in PRTF’s. The primary purpose of the record review is to determine if the facility is complying with the restraint and seclusion requirements as evidenced by:
   1) documentation of the entire emergency situation and all events surrounding it;
   2) the outcomes of the emergency safety intervention; and
   3) the health and well being of the residents.

Other pertinent information - Early in the survey, review seclusion and restraint records for any evidence or trends that suggests these procedures are being overused. Review any other source that may have impact on these requirements including accident and incident profiles for any evidence that residents are being abused, abusing each other, or are vulnerable to abuse and injury. If there is evidence of physical, verbal, or sexual abuse, surveyors should follow-up on the status and condition of those residents if they are still in the facility and identify the outcome of this review. All team members should participate in reviewing pertinent information. Surveyors should refer also to Appendix Q regarding immediate jeopardy as found within the SOM.

Documentation - Record any other documents reviewed on form CMS-807. Clearly delineate the documentation as documents reviewed.

TASK 3 - OTHER RECORD REVIEWS

A. Death Records - Review a list of all resident deaths, since the last survey. All team members participate in the record review of residents who have died.

   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.

   Documentation – For death records, refer to form CMS-726, CMS Death Record Review Data Sheet.

B. Policy and Procedures – Review a PRTF’s policy and procedure documents on restraint and seclusion.

C. Incident and Accident Reports – Review a PRTF’s incident and accident reports for at least six months prior to the date of the present survey. Some State laws may 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. PRTFs should provide this summary, as well as the applicable state law, within one working day of the entrance interview.

TASK 4 - DIRECT RESIDENT OBSERVATIONS
Purpose – Determine through direct observations if a therapeutic relationship exists between staff and the residents. Staff must respect the rights of the residents and interact with them in a mutually productive manner. Also observe if staff utilizes de-escalation and other behavior management techniques when a situation warrants such intervention. De-escalation techniques include mediation, conflict resolution, active listening techniques, and verbal and observational methods.

Observe each sampled resident (after obtaining the resident's permission) in as many treatment modalities (groups, activities, treatment team meetings, other types of meetings, and milieu interactions in the resident's environment) as possible. Visit as many of these modalities as time allows. Conduct observations over as much of the day and evening time span as possible; team members may choose to alter their work schedules so that observations can be made during most of the residents' waking hours. It is not appropriate to ask 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 see the resident during the survey.

Documentation - Record all observations on form CMS-3070I. If this disrupts the activity in progress, document after observations are completed.

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 treatment modality was in progress);
- What the staff is doing
- The presence of disruptive behavior, and staff’s intervention, if any;
- Any other pertinent information

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. Consent is required for all resident’s involved in sample, however if other children are observed in the process consent is not required unless the surveyor seeks to obtain further identifying information on other children in observation.

TASK 5 INTERVIEWS

Resident Interviews - Interviews with residents consist of questions directed at determining the resident's understanding of their seclusion or restraint 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 seclusion or restraint usage. Also ascertain if the resident felt that the restraint or seclusion was warranted based on their behavior. Interviewing a resident takes place after asking staff if the interview will not disturb that resident. 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 for that resident will consist of observations 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.

Setting:
1. Request permission of the resident to talk.
2. Provide the resident with information such as surveyor name and purpose of the survey.
3. Ensure resident confidentiality by conducting the interview in an appropriate location. Staff should be easily available and may be present in the room, but should not be able to overhear conversation.

Suggested questions:
• Can you tell me why you are in this facility?
• Can you tell me about the last time that you were restrained/secluded in time out?
• Where was staff situated 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.
• What caused the need for restraint/seclusion/time out?

Age Appropriate Adjustments – Surveyors should keep in mind residents who reside in PRTFs range in age from toddlers to adolescents or young adults. Thus, adjustments in the manner and descriptions should change according to the understanding of the resident. For example, kneeling or sitting in a chair may be more appropriate to begin a conversation. Also asking a question such as “Can you tell me why you are in this facility?” can be reworded to ask a series of probing questions to get at an 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 also note that different facilities and different children will interpret these procedures (restraint/seclusion) based on their own frame of reference. Facility staff should be used to help in clarifying the meanings.

Staff Interviews – Restraint, seclusion and time out procedures involve two main participants, the resident and the staff. After interviewing the resident, it is also equally important to interview staff to ascertain their understanding of the facilities restraint and seclusion policies. In order to ensure safety, staff must be adequately educated and oriented to their work environment. Staff should also be familiar with the resident’s treatment plan to facilitate the resident’s attainment of the goals established. Assess for consistent treatment approaches among disciplines as well as the outcomes experienced by the residents. Interview the following:

• Assigned responsible staff member (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 the interviews, ask questions that elicit information about:

• How the staff integrates treatment plan goals and objectives that have been developed as a result of seclusion or restraint episodes.
• How a need for restraint or seclusion is determined.
• How staff implement and discontinue time out, restraint or seclusion.
• What behavior typically warrants interventions such as restraint or seclusion?
• If staff feels prepared (through education and training) to work and interact with residents.

Interviews with Parents and Legal Guardians – 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 informed of the facility 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 Major Department Directors and/or Facility Leadership – 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 - Record each interview conducted with residents/parents/legal guardians and staff onto form CMS-807. Clearly delineate the documentation as an interview. Include 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
- Summary of information obtained.

Parent/ Legal Guardian
- Relationship to the resident.
- 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.

TASK 6 - VISIT TO EACH AREA OF THE CERTIFIED FACILITY SERVING RESIDENTS

Purpose - By the end of the survey, visit each place where residents of the facility are permitted to spend their time, both structured and unstructured, as these are places where an unanticipated behavior may occur that would require immediate emergency interventions. The room used for seclusion must be evaluated. Also examine the location where restraints are stored as well as those items that the facility uses as a restraint. Other examples of areas to visit are: cafeteria, bedrooms, and classrooms.

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. Record any pertinent observations in the appropriate document. The visit or tour can be conducted at any time during the course of the survey.

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.

Always get permission before entering a resident’s room. If it is necessary to observe a treatment procedure, or to observe a resident who is exposed, courteously ask permission from the resident if she/he comprehends, or from the staff if the individual cannot communicate. If resident physical contact is required to note a treatment or visually examine an injury, a facility nurse or physician, not the surveyor, should touch the resident. In some instances, visual inspection of an injury may not be appropriate depending on the location of the injury. Surveyors should always ensure that they are respecting the privacy of the resident.

Documentation - Record all observations and findings in form CMS-807. Clearly delineate the documentation as visiting various areas of the facility.
Pre-exit Meeting - The team leader ascertains that all survey team members have completed their respective survey tasks prior to the surveyor pre-exit meeting. At this meeting, the surveyors will share their respective findings, and make team decisions regarding compliance with each standard and the Condition of Participation. All necessary forms applicable include:

- CMS-2567 Statement of deficiencies and Plan of Correction
- CMS-807 Surveyor Notes Worksheet
- CMS-3070I Individual Observation Worksheet

And if applicable
- CMS-726 CMS Death Record Review Data Sheet

General - Transfer to the CMS-2567 all examples of evidence obtained from observations, interviews, and record reviews. Transfer those findings 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(ies) 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.

Pre-exit conference --Surveyors hold a pre-exit survey team conference at the conclusion of the survey prior to the exit conference and come to an agreed judgment on the severity of any deficiencies and whether their number, character, and combination interfere with the delivery of adequate care, and create hazards to residents’ health and safety. 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. This would be the basis for a finding of noncompliance.

Exit Conference.—Following the pre-exit conference held to allow team members to exchange and formulate survey findings, the surveyors conduct an exit conference (“an exit”) with the PRTF’s administrator, designee, and other invited staff. The purpose of the exit conference is to informally communicate preliminary survey team findings and provide an opportunity for the interchange of information.

Although it is CMS’ general policy to conduct an exit conference, be aware of situations that would justify refusal to continue an exit conference. For example, if the PRTF is represented by counsel (all participants in the exit conference should identify themselves), surveyors may refuse to continue the conference if the lawyer tries to turn it into an evidentiary hearing; other examples can be found in §2724 of the SOM. Also further discussed in §2724 are other helpful guidelines for surveyors including: Introductory remarks, ground rules, presentation of findings, and closure. Note that the discussion about Medicare participation and the RO, do not apply for Medicaid-Only PRTFs.

III. CMS- FORMS

CMS – 1539: Medicare/ Medicaid Certification and Transmittal - Form CMS – 1539 is used by the SA to certify findings to the RO or SMA with respect to the facility’s health and safety requirements. Form CMS – 1539 is also a transmittal cover sheet for the certification packet. The SA completes Part I of the form, while the SMA completes Part II. Together with the
certification file, Form CMS-1539 constitutes the primary record of the determination to approve a provider or supplier. Refer to SOM §2762 for additional explanation.

CMS – 670: Survey Team Composition and Workload Report – The Survey Team Composition and Workload Report (Form CMS-670) is an integral part of the overall survey process. The SA completes this form for all survey and/or resurvey activities as it provides the necessary information on resource utilization applicable to survey activity in all Medicare and/or Medicaid providers and suppliers, and CLIA laboratories. Explanation for completing this form is found in Exhibit 74 of the SOM, as well as §2705 under SA survey team workload.

CMS – 801: Offsite Survey Preparation Worksheet – The Offsite Survey Preparation Worksheet (Form CMS-801) allows surveyors to document and highlight information they have gathered about a facility in preparation for their onsite arrival. The information that a surveyor should seek out includes complaints that have been filed against the facility, deaths or serious injuries reported, and any other information that may have impact on the focus of the survey or the sample of residents to be selected. Refer to SOM §2704, SA Pre-survey Preparation, for additional information.

CMS – 807: Surveyor Notes Worksheet - The Surveyor Notes Worksheet (Form CMS-807) will serve as one of the principal documents for surveyors to record information. Surveyors should use this form to record:

- Anecdotal notes and findings
- Areas of concern that warrant further investigation
- Interviews
- General observations of residents, staff or environment
- Resident sample

CMS – 3070I: Individual Observation Worksheet – This form is to be utilized for specific observation of each resident identified in the sample as well as general observations.

CMS – 726: CMS Death Record Review Data Sheet – The Death Record Review Data Sheet (Form CMS-726) is to be utilized in the event that the PRTF has had a resident death at the facility since the last survey. The surveyor is directed to review the autopsy report (if available), review the findings and recommendations of the Mortality Board and based on documentation in the record, to ascertain if the proper treatment was provided to the resident.


- It is the basic document disclosed to the public about the PRTFs deficiencies and what is being done to remedy them;
- It documents the specific deficiencies cited;
- It documents any promises made by the PRTF, i.e. plans for correction and timeframes; and
- It provides an opportunity for the PRTF to refute survey findings and furnish documentation that requirements are met.

Additional information regarding Form CMS-2567 and the plan of correction may be found at SOM §2728.
CMS – 2567B: Post-Certification Revisit Report – The Post-Certification Revisit Report (Form CMS-2567B) will be used in the event that a facility was found deficient in a Federal requirement. The SA will revisit the facility within a specified timeframe, as determined by State policies, to ensure that the Plan of Correction, as identified in form CMS-2567, was implemented and that the facility corrected the cited deficiency. Correction of cited deficiencies is documented on the 2567B when verified at the revisit. This document is an addendum to form CMS-2567. Further explanation discussing follow-up on Plan of Correction and Form CMS-2567B may be found at SOM §2732.
PART 2
Appendix

Regulations and Guidelines for the Use of Restraint or Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services for Individuals Under Age 21

Index

§483.352 Definitions
§483.354 General requirements for psychiatric residential treatment
§483.356 Protection of residents
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§483.366 Notification of parent(s) or legal guardian(s)
§483.368 Application of time out
§483.370 Post-intervention debriefings
§483.372 Medical Treatment for injuries resulting from an emergency safety intervention
§483.374 Facility reporting
§483.376 Education and Training
§483.352 **Definitions.**

For purposes of this subpart, the following definitions apply:

Drug used as a restraint means any drug that—

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

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

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

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

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

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

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

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

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

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

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

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

Interpretive Guidelines §483.354

Psychiatric Residential Treatment Facility (PRTF) means a facility other than a hospital, that provides psychiatric services, as described in subpart D of part 441 – Inpatient Psychiatric Services for Individuals Under age 21 in Psychiatric Facilities or Programs. PRTF’s must also ensure that they are in compliance with the requirements set forth in §441.151 through §441.182 which pertain to: certification for need of services, the team certifying the need for services, active treatment, individual plan of care and the team developing the individual plan of care.

Survey Procedures and Probes § 483.354

Ensure that the facility is accredited by either the Joint Commission on Accreditation of Healthcare Organizations, the Commission on Accreditation of Rehabilitation Facilities, the Council on Accreditation of Services for Families and Children, or by any other accrediting organization with comparable standards that is recognized by the State.

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

Interpretive Guidelines §483.356(a)

The facility must establish a policy for the use of any emergency safety intervention, which is defined in this subpart as the use of restraint or seclusion as an immediate response to an emergency safety situation. Seclusion or restraint may only be used for emergency safety situations, which are defined as unanticipated resident behavior that places the resident or others at serious threat of violence or injury if no intervention occurs. The use of restraint and seclusion should be selected only when other less restrictive measures have been found to be ineffective to protect the resident or others.

The facility policy should address all requirements set forth by this condition of participation (CoP) to ensure the protection of residents, which includes ensuring safety both during and after restraint or seclusion, specifying the required elements of an order for restraint and seclusion, identifying the staff who are responsible for continual assessment of a resident during restraint or seclusion as well as defining the minimal physical and psychological elements that must be assessed. The facility’s definition of restraint or seclusion should also correspond with the definitions as specified by CMS.

Survey Procedures and Probes §483.356(a)

Review policy:
• Ensure that the facility has a policy addressing the use of restraint and seclusion meeting the requirements as set forth in this CoP and interpretive guide.
• Ensure that the facility definitions of restraint and seclusion correspond with the definitions established by CMS.

**N-003**

§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 is not to be used as coercion, discipline, retaliation, and retribution or as compensation for lack of staff presence or competency. Examine closely how frequently emergency safety interventions are employed. Repeated applications of such interventions within short intervals of time may raise serious questions about the resident's right to be free from unnecessary restraint or seclusion.

**Survey Procedures and Probes §483.356(a) (1)**

1. Review resident records:
   • Is there a systematic pattern of restraint or seclusion usage?
   • Do the documented behaviors leading to restraint or seclusion usage provide clear evidence of risk to self or others?
   • Are problematic behaviors occurring only in certain situations, specific locations or at specific times (i.e., nights or weekends), possibly indicative of insufficient staffing?

2. Interview staff to determine:
   • Which resident behaviors typically warrant restraint or seclusion?
   • Which less restrictive interventions are usually attempted prior to seclusion or restraint?
   • What environmental, staffing or program issues make it difficult to manage residents with behavior issues?
   • Is frequent staff turnover an issue? If so, has the newly hired staff been appropriately oriented to their position?

3. Interview residents to determine:
   • If residents feel as if they are restrained or secluded for staff convenience.

**N-004**

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

**Survey Procedures and Probes  §483.356(a)(2)**

Review resident records:
• Are restraints or seclusion being implemented on a PRN or standing order basis?
• Verify that each order includes the justification and a specified time period for the restraint or seclusion.
• Evaluate any patterns of use and if appropriate orders were obtained.

**N-005**
§483.356(a)(3) Restraint or seclusion must not result in harm or injury to the resident and must be used only—

Interpretive guidelines §482.356(a)(3)

Staff must be appropriately trained on the correct application and safe usage of restraint or seclusion. Refer to N-070 to verify staff competence in ensuring safety to the resident.

Survey Procedures and Probes §482.356(a)(3)

Review incident and injury reports to determine if the injuries that have occurred are related to restraint or seclusion episodes.

N-006
§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 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.

Survey Procedures and Probes §482.356(a)(3)(i)

1. Review resident records to determine:
   • If documentation identifies the nature of the emergency safety situation.
   • If the unanticipated resident behavior could potentially harm themselves or others.

2. Interview staff to determine:
   • How the safety of the resident and others is ensured during an emergency safety situation.

N-007
§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 use of restraint or seclusion should be evaluated on a continual basis and ended at the earliest possible time based on the assessment and evaluation of the resident’s condition.

For example, if a resident has recovered from their unanticipated 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 also outline the criteria for discontinuing those interventions.

Survey Procedures and Probes §483.356(a)(3)(ii)

1. Review policies to determine:
   • If the policy includes criteria for discontinuing restraint or seclusion.
• If the policy does not address criteria for discontinuing the intervention, question how staff determines when to release the resident from the intervention.

2. Review resident records to determine:
   • If there is a pattern of residents staying in restraint or seclusion until the maximum time allowed by the order.
   • If documentation provides evidence that residents are taken out of restraint and seclusion when the emergency safety situation has ceased.

N-008
§483.356(a)(4) Restraint and seclusion must not be used simultaneously.

Survey Procedures and Probes §483.356(a)(4)

Review resident records to ensure that restraint and seclusion are not used at the same time.

N-009
§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)

Emergency safety intervention means the use of restraint or seclusion as an immediate response to an emergency safety situation. In emergency situations where an unanticipated behavior requires immediate protection of the individual or others, the measure chosen should be the least restrictive intervention possible. The intervention should be appropriate for the resident as well as the resident’s behavior.

Staff should document interventions that have been attempted prior to implementing seclusion or restraint. This effectiveness or ineffectiveness of interventions should be evaluated and incorporated into the resident’s treatment plan. That information should also be used as a basis for determining future interventions.

Survey Procedures and Probes §483.356(b)

Review resident records to determine:
1. If the intervention that was implemented took into account 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)

2. How is the consideration of the above factors documented in the record, specifically, in the treatment plan?
   • Is use of restraint or seclusion documented and reviewed by the treatment team?
- Is the use of restraint or seclusion addressed in the treatment plan?
- Have any antecedents to the behavior that warrants the use of seclusion or restraints been addressed?
- Has the success of previous interventions been discussed and incorporated into the treatment plan?
- Is the type of restraint used consistent with the resident’s behavior and physical/medical condition?
- How does the team ensure that all staff is aware of and understands the individualized treatment, specifically as it pertains to seclusion and restraints, for a resident?

N-010
§483.356(c) Notification of facility policy. At admission, the facility must—

(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)

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 the policy is provided at the time of admission.

Survey Procedures and Probes §483. 356(c )(1)

1. Determine how and when the facility notifies residents and their legal guardians/parents of the facilities policies on the use of restraint and seclusion.

2. Who is responsible to provide the resident or legal guardian/parents with this information?

N-011
§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)

The facility must ensure that all residents or parents/legal guardians understand the information that is presented to them. The facility should pay particular attention to individuals who need assistive devices (e.g., magnifying glass, Braille, sign language), or have a communications challenge, such as deafness, low vision, blindness, or not being proficient in English, to ensure that communications are clear.

Survey Procedures and Probes §483. 356(c )(2)

1. Interview staff to ascertain if applicable staff knows which steps to take to acquire alternate means of communication.
   - How is a communication barrier identified? By whom?
- Does the facility have alternative means, such as written materials in other languages, documents in Braille or large print, or interpreters to communicate with residents or parents and legal guardians, when necessary?
- Review the material and verify the process to obtain services, such as an interpreter.

2. Interview the resident and/or parent/legal guardian to determine the effectiveness of the facility’s communication of the restraint or seclusion policy. If possible, add any resident and/or parents/legal guardians that may have a communication barrier to assess effectiveness of facility communication.
   - Does this person understand the policy?
   - Did the facility effectively communicate with them?

N-012
§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

Survey Procedures and Probes §483.356(c)(3)

Review the resident’s record for a signed acknowledgement of this communication with the resident and/or parent/legal guardian at the time of admission.

N-013
§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).

Survey Procedures and Probes §483.356(c)(4)

1. Review the facility policy and procedures to ascertain that a copy is to be provided to the resident or parent/legal guardian.

2. Interview residents and parents/legal guardians to determine if they received a copy of the policy at admission.

N-014
§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 information must be provided to the resident and/or parent/legal guardian at admission. The contact information must be presented in a manner or language understandable to the resident. If the facility is unsure of which State Protection and Advocacy (P&A) organization to refer the resident, the facility may provide the contact information for the national P&A organization.
Survey Procedures and probes §483.356(d)

1. Review facility policy and procedures to verify the P&A contact information is provided at admission.

2. Interview residents’ and/or parents/legal guardians to determine
   - If they received the information
   - If they understood the information provided to them
   - If they understood what type of information should be reported to the P&A organization.

N-015

§483.358 Orders for the use of restraint or seclusion

(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 recipients under age 21 are provided under the direction of a physician.

Interpretive Guidelines §483.358(a)

The Psychiatric Residential Treatment Facility’s policy should conform to state law, indicating which physician or other licensed practitioner permitted by the State to order restraint or seclusion and trained in the use of emergency safety interventions are permitted to order restraint in that facility.

An order must be given regardless of the expected length of time the restraint or seclusion lasts, 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.

Survey Procedures and Probes §483.358(a)

1. Review policy to determine:
   - If the policy describes who is responsible for ordering restraint or seclusion. Is the policy consistent with state law?
   - If the policy requires that all services are provided under the direction of a physician.

2. Review resident records to determine:
   - If the use of restraint or seclusion is associated with an order.
   - Who ordered the intervention?
   - If services are provided under the direction of a physician.

3. Interview licensed personnel to determine who may order restraint or seclusion and how and when that order is obtained and documented.

4. Determine whom the State recognizes as an “other licensed practitioner permitted by the State and the facility to order restraint or seclusion and trained in the use of emergency safety interventions”.
   - What are the facility policies and methods to ensure that these physicians or licensed practitioners are properly credentialed and licensed to order seclusion or restraint?
N-016
§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 “treating” physician is the physician who is responsible for the management and care of the resident. If the treating physician did not order the emergency intervention, it is important to consult with the treating physician, as soon as possible, because information regarding the resident’s history may have a significant impact on selection of seclusion or restraint intervention.

Survey Procedures and Probes §483.358(b)

Review resident records to determine if the treating team physician ordered the restraint or seclusion.

- If the treating physician did not order the intervention, is documentation of contact with the treating physician included in the record? Refer to N-033
- Does the treating physician order restraint or seclusion when he/she is available?

N-017
§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.

Survey Procedures and Probes §483.358(c)

1. Review relevant sections of the policies and procedures regarding the authorized types of interventions that may be used in the facility.

- Does facility policy indicate which interventions are least restrictive to most restrictive?

2. Review the resident’s record and interview staff to determine

- If the safety intervention used was appropriate for the resident based on their treatment plan
- Does the record reflect changes in behavior and staff concerns regarding potential danger on the unit/ward prompting use of seclusion or restraints?
- If other less restrictive interventions were considered or attempted and documented

N-018
§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 Psychiatric Residential Treatment Facility’s policy should conform to state law. The policy should also indicate who could receive a verbal order. The policy should also include the time frame in which a physician or licensed practitioner should co-sign the verbal order.

Survey Procedures and Probes §483.358(d)

1. Review policies and procedures to determine
   - Who may receive an order for restraint or seclusion. Does it specify a registered nurse or other licensed staff?
   - Who must be available to staff for consultation.
   - If the facility’s policy is consistent with state law.

2. Review verbal orders within resident records to determine
   - If the appropriate person received the order
   - Has the appropriate person verified a verbal order in a signed written form?
   - Was the verbal order verified in a signed written form within the time frame specified by the facility?

3. Interview licensed staff to determine
   - Who receives the order for restraint or seclusion
   - If someone who can order restraint or seclusion has been available for consultation.
     Look for documentation of consultation with someone who is authorized to order restraint or seclusion.
   - Has staff experienced any difficulty obtaining telephonic consultation?

4. Determine who the State recognizes as other licensed practitioner permitted by the State and the facility to order restraint or seclusion and trained in the use of emergency safety interventions or as having the authority to order restraints or seclusion.

N-019
§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.
The use of restraint or seclusion must be limited to the duration of the emergency safety situation regardless of the length of the order. The time frames specified in these requirements are maximums per age group. The ordering practitioner has the discretion to decide that the order should be written for a shorter period of time; and in the meantime, 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 the 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.

Survey Procedures and Probes §483.358(e)(1) and (2)

1. Review policies and procedures regarding time frames of emergency safety interventions. Ensure they are consistent with regulation.

2. Review resident records for time frames of restraint or seclusion. Ensure that the ordered time frame and the actual time frame that the resident is restrained or secluded is consistent with the policy.

3. Interview personnel to determine whether restraint or seclusion end when the emergency safety situation ends.
   - If the time of restraint use is outside the limits of the order, look for evidence that the behaviors necessitating the restraint use have persisted. Is there evidence to indicate that the staff have evaluated whether the restraint can be safely removed or seclusion discontinued?
   - Look for evidence that the restraint and seclusion ended when the emergency safety situation ended. Did restraint or seclusion end before the ordered time? Does documentation indicate the restraint or seclusion was terminated early because it was no longer needed? Have ongoing assessments been performed?
   - Look for evidence of consecutive orders.
   - Are time frames for restraint and seclusion age appropriate as specified in this regulation?

N-020 §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.

Interpretive Guidelines §483.358(f)(1) through 483.358(f)(4)

A physician or other licensed practitioner (as recognized by State law and psychiatric residential treatment facility policy) evaluation of a resident must be face-to-face. A telephone call is not adequate in accordance with this regulation. The assessment ensures the resident’s rights, assures the restraint or seclusion is necessary and appropriate and also allows the practitioner to evaluate the medical status of the resident.

If a resident who is restrained or secluded is released before the physician or other licensed practitioner arrives to perform the assessment, the physician or other licensed practitioner must still see the resident face-to-face to perform the assessment within one hour after the initiation of this intervention.

Survey Procedures and Probes §483.358(f)(1) through 483.358(f)(4)

1. Review facility policy to determine how, when and by whom residents are to be assessed.

2. Review resident records for the 1-hour assessment:
   - Are assessments being performed within the specified timeframe? Does the appropriate person perform them?
   - Is the assessment is face-to-face?
   - Does documentation verify that all required elements below (1-4) are being assessed?
     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

N-021
§483.358(g) Each order for restraint or seclusion must include—

Interpretive Guidelines §483.358(g)

To ensure that orders are complete and provide essential direction to the staff that is responsible for implementing those orders, each order for seclusion or restraint has elements that must be included to ensure validity and appropriateness of the order. These elements must include the name of the person ordering, date and time of the order, the specific restraint or seclusion ordered and the maximum amount of time that the resident may be either secluded or restrained. If any of these elements are missing from the order, then that order was not valid and should not have been implemented without clarification to address all required elements.

N-022
§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;
Survey Procedures and Probes §483.358(g)(1)

Review the resident’s record to ensure that the name of the ordering physician or licensed practitioner is clearly documented.

N-023
§483.358(g)(2) The date and time the order was obtained; and

Survey Procedures and Probes §483.358(g)(2)

Review the resident’s record to ensure that a date and time is documented when the order was obtained.

• Is the date and time of the order consistent with all other documents and logs related to the restraint or seclusion incident?

N-024
§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.

Survey Procedures and Probes §483.358(g)(3)

1. Review the facilities’ policies relating to seclusion and restraints
   • Are time limits specified? Refer to N-019 for age specific time limits.

2. Review resident’s record for the restraint or seclusion order that was to be implemented:
   • Is the specific type of restraint or seclusion to be implemented clearly specified?
   • Is a maximum time frame specified?
   • Is the maximum length of time ordered for use of this safety intervention consistent with the timeframes specified in the policy?
   • Was this restraint or seclusion ordered by a physician or licensed practitioner who is recognized by the facility to order it?

N-025
§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)

A qualified staff person (as determined by the facility) must fully document events leading up to, during and after the implementation of the restraint or seclusion as specified by §483.358(h)(1-5).

If the resident is still restrained or secluded at the end of the 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 safety intervention is required to document any activity relating to the duration of the seclusion or restraint and the discontinuation of that safety intervention.

Survey Procedures and Probes §483.358(h)

Review resident record to determine:
- That documentation is recorded at the end of the shift in which the resident has been removed from restraint or seclusion.
- If the resident was restrained or secluded during a period that covers multiple shifts, that the staff who witnessed the initial safety situation documented their first hand account.
- Compare the documented times of the staff notes to the implementation and discontinuation times of the intervention – are they consistent?
- If the documentation provides a clear and accurate picture of the events that occurred.

N-026
§483.358(h)(1) Each order for restraint or seclusion as required in paragraph (g) of this section.

Survey Procedures and Probes §483.358(h)(1)

Review the record to determine if staff addresses the order in the documentation.

N-027
§483.358(h)(2) The time the emergency safety intervention actually began and ended.

Survey Procedures and Probes §483.358(h)(2)

Review the record for start and discontinuation times of the restraint or seclusion.
- Is the start and end time consistent with the timeframes specified in the order?

N-028
§483.358(h)(3) The time and results of the 1-hour assessment required in paragraph (f) of this section.

Survey Procedures and Probes §483.358(h)(3)

Review resident record to determine:
- If the 1-hour assessment is documented.
- If staff documentation addresses the physician’s or licensed practitioner’s 1-hour assessment findings.

N-029
§483.358(h)(4) The emergency safety situation that required the resident to be restrained or put in seclusion.
Review resident record to determine:
- If the actual behavior exhibited by the resident, which warranted restraint or seclusion, is documented.
- Did documentation include any less restrictive interventions that were attempted?
- Did documentation describe any known antecedents to the behavior?

N-030
§483.358(h)(5) The name of staff involved in the emergency safety intervention.

Survey Procedures and Probes §483.358(h)(5)

Review the record to ascertain the names of all staff that were involved in the intervention.

N-031
§483.358(i) The facility must maintain a record of each emergency safety situation, the interventions used, and their outcomes.

Survey Procedures and Probes §483.358(i)

Review the facility policy for maintaining a record on each restraint or seclusion.
- Do record keeping policies conform to state requirements?
- How is this information used? Is it used for quality improvement activities?

N-032
§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)

Verbal orders that were obtained by a registered nurse or other licensed staff should be signed by the physician or licensed practitioner within 24 hours of the order being issued. The 24-hour time frame is not required specifically by regulation. If the facility uses another time frame, ensure that the time frame is “as soon as possible.”

Survey Procedures and Probes §483.358(j)

1. Review the facility policies on verbal orders.
   - What timeframe is specified for signing verbal orders? If the facility allows for a longer period of time for signatures on verbal orders than 24-hours, ensure that the timeframe is “as soon as possible”.

2. Review the order for the physician or licensed practitioner signature.
   - Are the orders signed within the timeframe specified in facility policy from the time of the original order?
N-033
§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—

(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. The ordering provider also has an obligation to inform the treating physician of the events that transpired which led to the order for emergency intervention. It is important to consult with the treating physician, as soon as possible, because the emergency safety intervention/situation affects the treatment plan.

Survey Procedures and Probes §483.360(a)

1. Review the facilities’ policies and procedures for prompt notification to the treating physician when someone other than the treating physician orders seclusion or restraint.

2. Review resident records to determine:
   • If contact with the treating physician if he/she did not order the restraint is documented.
   • If the records contain evidence that reflect facility policies and procedures for appropriate notification of the treating physician.

N-034
§483.360(b) Document in the resident's record the date and time the team physician was consulted.

Interpretive Guidelines §483.360(b)

If the ordering physician is not on site to document that the consultation took place, the treating team physician may note in the record that he/she was consulted by the ordering physician.

Survey Procedures and Probes §483.360(b)

Review resident record to determine:
   • If documentation is evident as to when the treating physician was consulted and by whom.
   • If documentation is not found, ask the appropriate staff how the treating physician is informed about the incident? By whom? How is this notification documented?

N-035
§483.362 Monitoring of the resident in and immediately after Restraint
(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)

Clinical staff monitoring a resident in restraints should take into account the individualized assessment including both physical and psychological factors of the resident. Facility policies and procedures should specify who is clinically trained and appropriate to monitor residents in restraint. Those policies should also include clearly specified criteria for the use and discontinuance of restraints. Continual assessment of the resident should also result in release from restraint as soon as possible.

Survey Procedures and Probes §483.362 (a)

1. Review the facility's policy on restraint to determine how the facility is continually assessing and monitoring resident physical and psychological status.
   • Does facility policy specify which staff members are responsible for assessing and monitoring the resident?
   • Is the mental status assessed? How is this documented?
   • Is the physical status, (i.e., vital signs, skin integrity, circulation) assessed? How is this documented?

2. Is the resident assessed regarding continued need for use of restraint? Is there adequate justification for continued use and is this documented?

3. Verify documentation of the resident’s response to and during restraint usage and the effectiveness of the intervention.

4. How is the individual's safety ensured?

5. Verify where staff is located while a resident is in restraints.

6. Are injuries reported and documented during restraint usage?

7. Review facility incident/injury reports for injuries reported during or following restraint usage. Refer to N-063.

N-036

§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 §483.364(b)

The facility should have clear criteria for the use and discontinuance of restraints. If necessary, prior to the expiration of the original order, a registered nurse or other licensed staff
can telephone the physician or other licensed practitioner, report the results of his/her most recent assessment and obtain further instruction.

Survey procedures and Probes §483.364(b)

Review resident records to determine:
- Is there a pattern of remaining in restraints beyond the order?
- Is there documentation of behaviors that warrant continued use of restraints?
- Is there evidence that the physician or licensed practitioner was notified of the situation?
- Who contacted the physician or licensed practitioner?
- Were additional instructions given and followed? Was the outcome documented?

N-037
§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)

The expectation is that this assessment is conducted in person (i.e., face-to-face). Also, dependent on state law, other licensed practitioners such as registered nurses, physician’s assistants or nurse practitioners may be performing this assessment.

Survey Procedures and Probes §483.362(c)

Review resident records to determine:
- If an evaluation of the resident’s well being was documented after release from restraint.
- Is the evaluation conducted in person?
- Who performed the evaluation?
- If not a physician, how is the licensed practitioner qualified to perform the evaluation? What training has the licensed practitioner had that ensures their ability?

N-038
§483.364 Monitoring of the resident in and immediately after seclusion.

(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)

Clinical staff monitoring a resident in seclusion should take into account the individualized assessment including both physical and psychological factors of the resident. Facility policies and procedures should specify who is clinically trained and appropriate to monitor residents in restraint. Those policies should also include clearly specified criteria for the use and
discontinuance of restraints. Continual assessment of the resident should also result in release from seclusion as soon as possible.

Survey Procedures and Probes §483.364(a)

1. Review the facility's policy on seclusion to determine how the facility is continually assessing and monitoring resident physical and psychological status.
   - Does facility policy specify which staff members are responsible for assessing and monitoring the resident?
   - Is the psychological status assessed? How is this documented?
   - Is the physical status (i.e., vital signs, skin integrity, circulation, etc.) assessed? How is this documented?
   - Verify that the facility does not use video monitoring as a substitute for clinical staff monitoring.

2. Review resident records to determine:
   - Is the resident assessed regarding continued need for use of seclusion?
   - Is there adequate justification for continued use and is this documented?
   - Is there documentation of the resident’s response to and during seclusion and the effectiveness of the intervention?

3. How is the individual's safety ensured?

4. Verify where staff is located while a resident is in seclusion.

5. How does staff reintroduce residents into the environment after the resident has been secluded?

6. What action does staff implement if a resident in seclusion becomes self-injurious, exhibits behaviorally inappropriate actions such as urinating on the floor or shows signs of physiologic illness?

N-039
§483.364(b) A room used for seclusion must—

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

Survey Procedures and Probes §483.364 (b)(1)

1. Verify whether or not anyone standing or lying in any position, in any part of the room can be seen.
2. Verify which room the facility designates as a seclusion room.
3. Where does the monitor sit?

N-040
§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. There are other items that may be harmful to a secluded resident.

**Survey Procedures and Probes §483.364 (b)(2)**

1. Inspect the room to ensure that nothing is in the room that the resident may be injured by or may use to injure him/herself with.
   - Is there an easy mechanism to open and close doors?

2. During staff interviews and a review of the facility’s policy and procedures, ascertain how the facility addresses a potentially hazardous scenario such as this:
   - What if the resident somehow blocked the door to not allow admittance, either through a purposeful act or inadvertently (i.e. passes out in front of the door, seizure, etc) and the staff is not able to push the door open?

**N-041**

**§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)**

The facility should have clear criteria for the use and discontinuance of seclusion.
If necessary, prior to the expiration of the original order, a registered nurse or other licensed staff can telephone the physician or other licensed practitioner, report the results of his/her most recent assessment and obtain further instruction.

**Survey procedures and Probes §483.364(c)**

Review resident records to determine:
- Is there a pattern of remaining in seclusion or restraint beyond the order?
- Is there documentation of behaviors that warrant continued use of seclusion?
- Is there evidence that the physician or licensed practitioner was notified of the situation?
- Who contacted the physician or licensed practitioner?
- Were additional instructions given and followed? Was the outcome documented?

**N-042**

**§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 §483.362(d)**
The expectation is that this assessment is conducted in person (i.e., face-to-face). Also, dependent on state law, other licensed practitioners such as registered nurses, physician’s assistants or nurse practitioners may be performing this assessment.

Survey Procedures and Probes §483.362(d)

Review resident records to determine:
- If an evaluation of the resident’s well being was documented after release from seclusion.
- Is the evaluation conducted in person?
- Who performed the evaluation?
- If not a physician, how is the licensed practitioner qualified to perform the evaluation?
  Are they recognized by State law to perform this function?

N-043
§483.366 Notification of parent(s) or legal guardian(s).

If the resident is a minor as defined in this subpart:

(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 the 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).

The policy should also specify what information should be relayed to the parent or legal guardian. Facility written polices and procedures should also address: (1) required record documentation; (2) definition of “as soon as possible;” (3) indicate which staff is responsible (i.e. by title or position) for notifying the restrained or secluded resident’s parent(s) or legal guardian(s); (4) what should be done if the parent(s) or legal guardian(s) does not want to be contacted and the required documentation; (5) staff’s inability to successfully contact the restrained resident’s parent(s) or legal guardian and the required documentation.

Survey Procedures and Probes §483.366(a)

1. Review policy to determine:
- Whether the facility’s policy follows the expectations of the notification requirement.
- The facility’s policy for notifying parent(s) or legal guardian(s) of emergency safety interventions.
- The facility’s polices and procedures for prompt notification of parent(s) or legal guardian(s) when seclusion or restraint has been initiated.
- Does the policy specify who should contact the parent or legal guardian and does it specify what information should be reported?
2. Does the facility notify the parent(s) or legal guardian(s) of this policy upon admission? Refer to N-010.

3. Is there evidence that the facility has a system in place to assure that a resident’s parent(s) or legal guardian(s) is contacted as soon as can be reasonably expected after the resident is restrained or secluded?

4. Interview staff to determine their knowledge of the facility’s policy regarding the contacting of parent(s) or legal guardian(s) after the initiation of each emergency safety intervention.

N-044
§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.

Survey Procedures and Probes §483.366(b)

1. Review resident records to determine:
   • If evidence of compliance with notification of parent(s) or legal guardian(s) of emergency safety interventions is documented.
   • Verify the individual who was contacted and the specific time the contact was made.
   • Determine if records reflect compliance with the facility’s policies and procedures.
   • Is there clear documentation describing any unsuccessful contact attempts?

2. Does the facility employ alternative methods, in accordance with policy, for contacting the parent or legal guardian?

3. 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.

N-045
§483.368 Application of time out.

(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.

Survey Procedures and Probes §483.368(a)

1. Review policy to determine:
   • If the facility time out policies adhere to the federal definitions.
   • How and by whom is time out implemented and discontinued?
   • How often and by whom is time out documented?
2. Interview staff to determine:
   • What happens if a resident leaves time out before the staff think it is appropriate?
   • What type of behavior warrants time out? Prior to implementation, are residents assessed for any risks associated with time out?
   • How long does time out usually last?
   • What training does the facility provide to their staff on this particular intervention? Also review N-069.

N-046
§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(a)

Exclusionary 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 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.

Survey Procedures and Probes §483.368(a)

1. Does the policy specify where time out may occur?
   • Does the policy specify any documentation requirements for time out?

2. Interview staff and residents to determine:
   • Where time out typically occurs
   • If this intervention is used often.
   • How does staff document this intervention?

N-047
§483.368(c) Staff must monitor the resident while he or she is in time out.

Survey Procedures and Probes §483.368(c)

1. Review policy to determine:
   • Does the policy address monitoring of residents during time out?
   • Does the policy ensure the well being of the resident?

2. Interview staff to determine:
   • How is a resident monitored during time out?

§483.370 Post intervention debriefings.

N-048
(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.

Survey Procedures and Probes §483.370(a)

1. Review resident records to determine:
   - If appropriate staff was involved in the face-to-face debriefing;
   - If the resident was present for the debriefing;
   - If the resident is a minor, were the parents or legal guardians notified and given an opportunity to participate in the debriefing?
   - Has the facility identified an alternative or a means to eliminate the use of restraint and seclusion for the individual?
   - Does the treatment plan reflect changes as a result of the debriefing?

2. Interview residents to determine:
   - If they participated in a debriefing.
   - Did they have an opportunity to actively discuss the emergency safety situation and intervention?
   - Were strategies to prevent future use of seclusion or restraint discussed?
   - If they felt that they contributed to the discussion.

3. Interview staff to determine:
   - If a face-to-face debriefing occurred within the 24-hour expectation.
   - Did the debriefing process identify behavioral triggers?
   - Was the debriefing conducted in a meaningful way to them?

Determine if communication barriers existed and, if so, did the facility make the necessary accommodations?

N-049

§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 –

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

Survey Procedures and Probes §483.370(b)(1)
1. Review policy to determine:
   - That a debriefing of all involved staff within 24-hours of an emergency safety intervention is required.
   - Does the policy specify what should be discussed in a debriefing?

2. Interview staff to determine:
   - If discussion included identification of precipitating factors.

N-050
§483.370(b)(2) Alternative techniques that might have prevented the use of the restraint or seclusion;

Survey Procedures and Probes §483.370(b)(2)

Interview staff involved in the safety intervention to determine.
   - If staff can identify any alternate interventions that would/ could have prevented the use of the emergency safety intervention.
   - Was this discussed in the debriefings?

N-051
§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

Survey procedures and Probes §483.370(b)(3)

1. Interview staff to determine:
   - Were any procedures to prevent recurrence of restraint or seclusion discussed?
   - Was a plan of action determined?

2. Has the resident’s treatment plan been updated to include alternate interventions or procedures?
   - How is this implementation shared with staff?

N-052
§483.370(b)(4) The outcome of the intervention, including any injuries that may have resulted from the use of restraint or seclusion.

Survey Procedures and Probes §483.370(b)(4)

1. Interview staff to determine:
   - If the outcome of the intervention was discussed.
   - Was anyone injured?

2. Did the emergency safety intervention result in injury to the resident or staff?
   - Are injuries documented in the resident’s record?
   - Review incident reports, seclusion and restraint logs to determine if residents or staff are injured during the emergency intervention.
N-053
§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.

Survey Procedures and Probes §483.370(c)

1. Verify, through review of the resident’s record, that both debriefings occurred.
   - Was staff directly involved in the emergency safety intervention included in both debriefings?
   - Are names of staff included in the documentation, both those who were present and those who were excused?

2. Review the treatment plan for modifications based on the debriefings.
   - Were the decisions made in the debriefings accurately reflected in the treatment plan?

N-054
§483.372 Medical Treatment for injuries resulting from an emergency safety intervention.

(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 assess the resident to determine the extent of any injuries and implement plans to administer appropriate medical care. It is also the responsibility of the facility to attain medical care immediately if the resident requires it. Staff that is medically trained to provide emergency first aid care and CPR should be available to provide the emergency medical interventions until further follow up emergency care can be provided.

Survey Procedures and Probes §483.372(a)

1. Verify facility policies and procedures to be used for emergency medical care resulting from implementation of safety interventions.
2. Verify and check that all available emergency equipment in the facility has documentation of appropriate and timely testing.

N-055
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 be responsible for assuring that one or more hospitals are available to receive residents in the case of an emergency.

Survey Procedures and Probes §483.372(b)

Review contracts/ affiliations/ transfer agreements to ensure currency.

N-056
§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.

Survey Procedures and Probes §483.372(b)(1)

1. Review policy to verify that the facility has specified the process of how to transfer a resident to a hospital.

2. Review records of those residents that have been transferred to a hospital for either medical or psychiatric care to ascertain if facility policies were followed.
   - Was the transfer conducted in a timely manner?

N-057
§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

Survey Procedures and Probes §483.372(b)(2)

1. Review policy to determine:
   - If the State medical privacy law regulations governing information that can be shared between treating institutions. Verify that the information shared between institutions is done in accordance with State law.
   - Policies should specify what information is required to be given upon transfer of a resident to a hospital and then also upon admission of a resident from a hospital.
   - Agreements between the PRTF and the hospital may outline in their protocols the required information that should be shared between the two entities.

2. Interview licensed staff to ensure they are familiar with and understand the policy.

N-058
§483.372(b)(3) Services are available to each resident 24 hours a day, 7 days a week.

Survey Procedures and Probes §483.372(b)(3)
1. Is the hospital with which the PRTF is affiliated available to provide care 24 hours a day, 7 days a week, including emergent care?

2. Is a staff person available to make a determination or contact someone who is capable of making a determination that a resident requires acute care during off hours such as weekends and nights?
   - Is the available staff person competent to recognize the need for acute care? Refer to N-071.

   **N-059**

   §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)**

   Complete documentation of any injury that resulted in the use of emergency medical care must be located in the resident’s record. A facility should have written policy and procedures that include all elements that must be included in this documentation. Staff injuries resulting from emergency safety intervention must be documented. Additional staff injury documentation may be kept in other facility documents.

   **Survey Procedures and Probes §483.372(c)**

   1. Review policy related to reporting of all injuries as a result of an emergency safety intervention. The policy should also indicate a timeframe in which injuries are to be reported and acted upon.

   2. Review staff injury data to verify expected requirements of documentation.

   **N-060**

   §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)**

   As part of the staff debriefing following the use of an emergency safety intervention, supervisory staff should process details of the incident including events leading up to the use of the intervention, description of the implementation of the intervention, any resident or staff injuries sustained during the altercation, and the resident’s response to the intervention. A review of the details of the incident will allow processing of problem solving techniques that could impact on developing alternative therapeutic approaches to future problems. This may be done through written documentation, verbal discussions with individual staff and in small groups. Outcomes of these discussions should be part of a facility’s plan to prevent future injuries. Refer to N-049, N-050, N-051, N-052.

   **Survey Procedures and Probes §483.372(d)**
1. Review all staff injury reports to determine if the facility developed and implemented a plan for preventing future injuries.

2. If possible, interview staff that may have been injured during a safety intervention to ascertain if the injury was discussed with a supervisor and if a plan was implemented to prevent future injuries.

**N-061**

**§483.374 Facility reporting**

(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.

**Survey Procedures and Probes §483.374(a)**

Determine from facility director if an attestation of compliance has been submitted and request to review a copy. The attestation should be submitted annually.
The minimal elements of an attestation include:

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 acknowledging the right of the State Survey Agency (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
8. 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
9. Name of individual and position of individual signing the attestation
10. The date that the attestation was signed

**N-062**

**§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) and (2)**
In order to be eligible to provide a Medicaid covered benefit and receive federal financial participation (FFP) for the provision of those covered services, a facility must have a provider agreement with any Medicaid Agency for which it provides services. For example, if a PRTF accepts residents from other states, then the PRTF is expected to have provider agreements with those other states.

Psychiatric residential treatment facilities must attest to being in compliance with CMS’ requirements regarding the use of restraint and seclusion. In the event of change of ownership or a new director, the facility is expected to re-attest.

Survey Procedures and Probes §483.374(a)(1) and (2)

1. Verify that the facility has provider agreements with all Medicaid agencies for which it provides services.

2. Verify that the current facility director has signed and submitted the attestation.

N-063

§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)

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. All serious injuries that require medical intervention are to be reported, regardless of whether it was 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 also to take steps to minimize the risk of more injuries.
The facility must report to the State Medicaid agency and the State designated Protection and Advocacy organization.

In preparation for a survey, all reports submitted by the facility to the above organizations should be reviewed.

Survey procedures and probes §483.374(b)(1)

1. Review policy to determine:
   - That “serious occurrence” is defined in a manner that is consistent with this regulation.
   - Ensure that the policy includes procedures that staff must follow in reporting serious occurrences.
   - Determine if the facility designates who should report and follow up on serious occurrences.
   - Does the policy adequately describe the serious occurrences, specifically injuries that should or should not be reported?
   - Is a policy present that addresses investigation of injuries of unknown origin? Does it include investigation of trends even if the cause of the injury is noted?

2. Interview staff to determine what method the facility uses to report serious occurrences.
   - Is staff able to differentiate between what should or should not be reported?

3. Review a random sample of serious occurrence reports/logs, etc. to determine if the facility is reporting serious occurrences timely.

4. Verify reports of serious occurrences with the State Medicaid agency and the Protection and Advocacy agency.

**N-064**

§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.

Survey procedures and probes §483.374.(b)(2)

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.

**N-065**

§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.

Survey procedures and probes §483.374(b)(3)

1. Review incident and accident logs for serious occurrences. Select a chart to review from the log if none are in the sample—refer to sample methodology.

2. Review the resident’s record to determine if the serious occurrence was reported to the appropriate agencies and adequately documented.

N-066
§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.

Survey procedures and probes §483.374(c)(1-2)

1. Review policy to ensure it includes clear instruction for documenting when and how to report deaths to CMS.

2. Verify that the facility has reported all deaths to the CMS regional office through documentation review of the deceased resident’s record.
   • Review documentation to determine if the facility is reporting by close of business the next business day after the resident’s death.

3. Interview staff to determine how and when the facility reports deaths to CMS’ regional offices.
   • Ask staff if a death has ever occurred at this facility.

4. Investigate any reports submitted to CMS and ensure that the number of reports submitted is the same as the number of deaths that have occurred at the facility.

N-067
§483.376 Education and Training
(a) The facility must require staff to have ongoing education, training, and demonstrated knowledge of–

Interpretive Guidelines §483.376(a)

The facility has the responsibility of requiring staff to attend ongoing training and education activities in required areas outlined below. It is imperative that the facility identifies staff that
has direct responsibilities to provide both care and treatment to the residents and ensures that those staff are appropriately educated and trained in their roles. It is also essential that staff that may not necessarily have direct responsibilities to provide care and treatment are also adequately trained and oriented to situations that may occur in their work environment.

N-068
§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 didactic and experiential training to staff that assists them in identifying and understanding psychiatric behaviors by the residents. Didactic 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. Experiential training is taught through “hands-on” experience, such as watching how a restraint is applied and then applying what was learned through a return demonstration. This training should include identifying staff roles and behaviors that affect the negative outcomes. Assessment of the impact of the resident’s environment should be evaluated to determine the factors contributing to the emergency situation.

Survey Procedures and Probes §483.376(a)(1)

1. Review policy to determine:
   • If facility policy and procedures outline the content that is to be taught to staff to ensure that they meet these requirements.
   • Is there evidence that the facility conducts training that is both didactic and experiential?

2. Through surveyor observation, does staff exhibit appropriate interactions with residents?

3. Interview staff to determine if they are oriented to the specific population of residents that they interact with.
   • Are staff able to implement the techniques that they are trained to use in an emergency safety situation?

N-069
§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 of therapeutic nonphysical intervention skills that can be used to identify a potential emergency safety situation. Through early identification of such situations, staff can then 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 didactic and experiential means.
The facility must also include training on the correct application of time out and how to monitor a resident in time out.

Survey Procedures and Probes §483.376(a)(2)

Verify that the facility has written policies, procedures and training documents that reflect the education and training in these areas.

N-070
§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. Identification of signs and symptoms of physical distress in resident’s system functions (circulatory, respiratory, skeletal, nervous), skin integrity must be included in the overall assessments during the use of emergency interventions. Staff responses to the identification of resident distress should include immediate interventions such as first aid, CPR, and removal of physical barriers impacting on the resident’s safe care.

Procedures and Probes §483.376(a)(3)

1. Verify that the facility has written policies, procedures and training documents that reflect the education and training in the safe use of restraint and seclusion.
2. Review incident reports related to seclusion and restraint.
3. Review staff training files to ensure currency of training.

N-071
§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 receives 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 are to be included in the facility training plans.

Survey Procedures and Probes §483.376(b)

1. Verify that the facility requires staff to be certified in CPR.
2. Review staff training files to ensure currency of training.
§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 of establishing and meeting guidelines and criteria of staff training credentials. The training requirements must demonstrate that staff trainers/instructors are educated, trained and experienced in the areas of expertise in which they teach. Personnel records must clearly reflect current educational training, and necessary recertification requirements. 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.

Survey Procedures and Probes §483.376(c)

1. Review personnel records of training staff and verify credentials as to appropriateness and current recertification updates.
2. Review contractual agreements and any procedure that the facility has for evaluating the services provided.

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

Survey Procedures and Probes §483.376(d)

Verify through training and staff personnel documents that training exercises were part of the education and training provided to the staff.

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

Interpretive Guidelines §483.376(e)

The training program for managing emergency safety situations must include competency evaluations on the materials and information provided. These competency evaluations must be observed and documented by the trainers.
The facility must include the requirement that all staff must be trained and receive documented evidence of demonstrated competency for participating in emergency safety situations before being an active staff member in these intervention techniques.

Survey Procedures and Probes §483.376(e)

Verify evidence of competence either in training records or personnel files.

**N-075**

§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)

The facility must provide documentation records of staff training in emergency safety situations that include: identification techniques to identify staff, resident behaviors and environmental factors that may be triggers, use of nonphysical intervention skills, safe uses of restraint and seclusion, recognition and responses to signs of physical distress in residents who are restrained or secluded. These training components (§483.376(a)(1) - (3) [N-067 – N-070]) are required on a semiannual basis. Documentation must include observed competencies in these areas.

The training documentation must also include records of re-certification in the use of cardiopulmonary resuscitation skills. This training is required on an annual basis.

Survey Procedures and Probes §483.376(f)

Verify evidence of these timed training requirements in the facility policies, training records and staff personnel files.

**N-076**

§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 provide in all staff personnel records all education and training that is provided. This documentation should include all successfully completed competency evaluations. The records should describe the dates the trainings were completed and the names of the responsible staff that certified the completion of the training components.

Survey Procedures and Probes §483.376(g)

1. Verify evidence of this documentation by reviewing staff personnel records.
2. Verify through the review of the training protocols that the facility includes these requirements in their training programs.
N-077
§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.