SUPPORTING STATEMENT
Condition of Participation - Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities Providing Psychiatric Services to Individuals Under Age 21 and Supporting Regulations at 42 CFR 483.350 - 483.376
CMS-R-306, OMB 0938-0833

Background

Section 1902(a)(9)(A) of the Social Security Act requires the State health agency or other State medical agency to establish and maintain health standards for private and public institutions in which recipients of medical assistance, under the State plan, may receive care or services. The Medicaid program makes Federal funding available for State expenditures under an approved State Medicaid plan for inpatient psychiatric services for eligible individuals under 21 years of age in hospital and non-hospital settings. Non-hospital settings, which we have defined as psychiatric residential treatment facilities, are replacing hospitals in treating children and adolescents with psychiatric disorders whose illnesses require a residential environment.

According to a GAO report issued in September 1999, improper use of restraint and seclusion can be dangerous to both people receiving treatment and to staff. The report stated that the full extent of related injuries and deaths from improper restraint or seclusion is unknown because there is no comprehensive reporting system to track injuries and deaths, or to track the rates of restraint or seclusion use by facilities. The information collection requirements in this regulation are intended to protect children and adolescents receiving services in these facilities from the dangers associated with the inappropriate use of restraint and seclusion.

A. Justification

1. Need and Legal Basis

On November 17, 1994, the Centers for Medicare & Medicaid Services (CMS) published in the Federal Register (56 FR 59624) proposed regulations to establish standards for non-hospital psychiatric residential treatment facilities, to be contained in a new subpart F of 42 CFR part 483. Among the proposed standards was a prohibition on physical restraints and psychoactive drugs for purposes of discipline or convenience, when not required to treat the resident's psychiatric symptoms, or when not specified in the plan of treatment. Also included was a prohibition on the use of involuntary seclusion. Moreover, limitations were proposed on the use of drugs in doses that would interfere with the resident's daily living activities, or the use of drugs to control inappropriate behavior. These drugs would not be used unless they were an integral part of a plan of care directed specifically toward reducing and eventually eliminating that behavior, or when the harmful effects of the behavior clearly outweighed the potential harmful effects of the drugs.

In March 1999, during the first session of the 106th Congress, members of the Senate and House of Representatives introduced three separate bills (S. 736, S. 750 and H.R. 1313) intended to protect individuals from the improper use of restraint or seclusion in Medicare and Medicaid-funded facilities. The bills reflected concern about the danger posed to residents in psychiatric residential treatment facilities as a result of improper restraint and seclusion practices. Improper restraint and seclusion practices can lead to serious injury and even death of residents as well as staff. These bills were incorporated into the enactment of the Children's Health Act of 2000, which was signed by the President on October 17, 2000.

Our interim final rule which published January 22, 2001, set forth a Condition of Participation (CoP) governing the use of restraint and seclusion that facilities must meet to provide, or to continue to provide, Medicaid inpatient psychiatric services to individuals under age 21. The rule set forth a series of standards, which a facility must meet to ensure each resident's physical and emotional health and safety. Further, it acknowledged each resident's right to be free from restraint or seclusion, of any form, used for purposes of coercion, discipline, convenience, or retaliation, and limited the use of restraint or seclusion to only emergency safety situations. It also imposed age-specific time limits for restraint or seclusion orders, and prohibited the simultaneous use of restraint and seclusion. Additionally, the rule required these facilities to report serious occurrences, including the death of a resident, a serious injury, or a resident's suicide attempt to the state Medicaid agency and, unless prohibited by law, to the state-designated Protection and Advocacy system. CMS added requirements governing the use of restraint and seclusion in these facilities to better protect children and adolescents from the dangers associated with the use of restraint or seclusion.

On May 22, 2001, we published an interim final rule amendment and clarification which became effective on that date. Specifically the amendment modified the facility reporting requirements to add an additional requirement that these facilities report any death of a resident to the CMS regional office.

2. Information Users

Section 1902(a)(9)(A) of the Act requires the State health agency or other State medical agency to maintain health standards for both private and public institutions in which recipients of medical assistance, under the State plan, receive services. The information collected under the requirements of this rule will assist States in monitoring the health and well being of Medicaid-eligible individuals who receive care in private and public facilities.

3. Improved Information Technology

While some facilities may be equipped to submit information electronically, we have no data on the total number of facilities with such capability.

4. Duplication of Similar Information

Through an informal review of several State regulatory requirements governing these facilities, we determined that the information collected is not currently being collected at the State level. We also inquired and verified with the National Association of Protection and Advocacy Systems, Inc. that they do not collect this information on a national or local level. Furthermore, we verified that the Joint Commission, the organization that accredits most of these facilities, does not require reporting of sentinel events. Any reporting of sentinel events by these facilities is on a voluntary basis.

5. Small Businesses

All of these facilities are considered small businesses for CMS' purposes and we have minimized reporting by these facilities to the extent possible. This collection has no significant economic impact on small entities.

6. Less Frequent Collection

Serious occurrences are reported on an incident by incident basis. Were CMS to require less

frequent reporting to the State Medicaid Agency, the Protection and Advocacy Organization, and the CMS regional offices, we would not be able to investigate serious occurrences timely thereby endangering the health and safety of children in these facilities.

7. Special Circumstances

The information collection requirements of the January 22, 2001, interim final rule required facilities to report serious occurrences involving residents to the State Medicaid agency, and unless prohibited by law, to the State-designated Protection and Advocacy organization. These serious occurrences must be reported to the Medicaid agency and Protection and Advocacy organization no later than the close of business the next business day following the occurrence. The information collection requirement of the May 22, 2001, interim final rule amendment required facilities to report only the death of a resident to the CMS regional office no later than the close of business the next business day following a resident's death. This information should be reported as quickly as possible to allow States, Protective and Advocacy organizations, and CMS to conduct timely investigations as to the cause of the serious occurrence, and to permit states to put safeguards in place to prevent further occurrences.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice published on January 13, 2012 (77 FR 2067). We received one comment from the American Psychiatric Association in which they stated that they do not find fulfilling these reporting requirements to be unduly burdensome. They also commended CMS for continuing to mandate this reporting requirement. No changes were made to this collection based on the comment received.

We published a notice of the information collection requirements contained in the amended Interim Final Rule in the Federal Register on 9/21/01, giving the public 60 days in which to comment on these requirements. Information collection requirements are not new and have been in effect since May 22, 2001.

As state earlier, we published an Interim Final Rule (IFR) with 60-day comment period on January 22, 2001. CMS had not provided prior notice of these information collection requirements for the purpose of soliciting public comment. We informally canvassed several states to ascertain if facilities are required to report this information and determined that facilities are not reporting serious occurrences to State Medicaid agencies or other organizations. CMS did not consult with States or P&A organizations about the information collection requirements prior to publication of this rule.

9. Payment/Gift to Respondents

No payments or gifts will be given to respondents.

10. Confidentiality

No assurances of confidentiality have been provided.

11. Sensitive Questions

No questions of a sensitive nature have been asked.

12. Estimates of Burden

Section 441.151 General requirements.

Paragraph (a)(4) of this section requires that inpatient psychiatric services for individuals under age 21 must be certified in writing to be necessary in the setting in which the services will be provided (or are being provided in emergency circumstances) in accordance with section 441.152. While this IFR is subject to the PRA, we believe the burden associated with this IFR is exempt in accordance with 5 CFR 1320.3(b)(2) because the time, and effort, and financial resources necessary to comply with this requirement would be incurred by persons in the normal course of their activities. These are reasonable and customary State practices and the State would impose this standard for efficient utilization of Medicaid services in the absence of a Federal requirement.

CMS estimates that there will be 80,000 patients who will have this information documented for them. Since we believe the burden associated with this requirement is exempt from the Act, we have assigned one (1) token hour of burden to this information collection requirement.

Section 483.356 Protection of residents.

Paragraph (c) of this section, Notification of facility policy, requires facility staff to inform each incoming resident (and, in the case of a minor, the resident's parent(s) or legal guardian(s)) at admission, 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 facility. Staff must obtain an acknowledgment, in writing, from the resident, or in the case of a minor, the resident's parent(s) or legal guardian(s), that he or she has been informed of the facility's policy. Staff must file the written acknowledgment in the resident's record.

In order to estimate the burden of this requirement on facilities, we used data from the CMS Certification and Survey Provider Enhanced Reports (CASPER) system. As of November 1, 2011, there are currently 376 psychiatric residential treatment facilities. Through an informal survey of providers, we estimate an average resident length of stay to be 9 months and based on a 9-month stay, each facility would admit an estimated average of 95 residents per year, or an estimated total of up to 35,720 residents (376 x 95 = 35,720). We believe it will take each facility 8 hours to develop a policy statement regarding the use of restraints and seclusion, and an average of 30 minutes to present the information to each incoming resident and the parent(s) or guardian(s), and to obtain and file the acknowledgment

Although there is a one-time burden of 3,008 hours (376 x 8 hrs = 3,008) nationwide to develop the statement, all of the 376 facilities have met this requirement. Additionally, there is an annual burden of 48 hours (.5 hours x 95 residents = 47.5 hours) per psychiatric residential treatment facility and 18,048 hours (376 x 48 hours= 18,048) nationally to disclose the policy.

[NOTE: The requirement to develop a policy statement is a one-time burden that has been met by all of the 376 facilities. Consequently, only new facilities need to develop a policy statement. The disclosure requirement is an ongoing requirement.]

Section 483.358 Orders for the use of restraint or seclusion.

In accordance with paragraph (d) of this section, a physician's or other licensed practitioner’s verbal order must be obtained by a registered nurse or other licensed staff

while the emergency safety intervention is initiated by staff, if a written order cannot be easily obtained. The verbal order must be followed with the physician's or other licensed practitioner’s signature verifying the verbal order.

While the information collection requirement in this paragraph is subject to the PRA, we believe the burden associated with it is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities.

In accordance with paragraph (h) of section 483.358 each order for restraint or seclusion must be documented in the resident's record. Documentation must include--

(1) The ordering physician or other licensed practitioner’s name;
(2) The date and time the order was obtained;
(3) The emergency safety intervention ordered, including the length of time for which the physician authorized its use;
(4) The time the emergency safety intervention actually began and ended;
(5) The time and results of any 1 hour assessments required in paragraph (f) of this section.
(6) The emergency safety situation that required the resident to be restrained or put in seclusion; and
(7) The name, title, and credentials of staff involved in the emergency safety intervention.

There are an estimated average of 47 situations per month per psychiatric residential treatment facility where restraint or seclusion is used equating to 564 situations (47 situation x 12 months = 564) per year, per facility, or approximately 212,064 (47 situations x 12 months x 376 PRTF = 212,064) situations nationally, per year. We estimate that it will take approximately 30 minutes per situation, or 282 hours annually per psychiatric residential treatment facility, for a national total of 106,032 hours (282 hours x 376 = 106,032) annually to comply with the documentation requirements.

In accordance with paragraph (i) of section 483.358, the facility must maintain an aggregate record of all emergency safety situations, the interventions used, and their outcomes.

Based on 15 minutes per situation, we estimate that it will take 141 hours per psychiatric residential treatment facility, and a national total of 53,016 hours (141 hours x 376 PRTFs = 53,016) annually to comply with this documentation requirement.

In accordance with paragraph (j) of this section, the physician or other licensed practitioner ordering the restraint or seclusion must sign the order in the resident's record as soon as possible.

While the information collection requirements in paragraph (j) is subject to the Paperwork Reduction Act (PRA), we believe the burden is exempt as defined in 5 CFR 1320.3(b)(2). The time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities.

Section 483.360 Consultation with treatment team physician.

Paragraph (a) of this section requires that, if the physician ordering the use of restraint or seclusion is not part of the resident's treatment team, the facility must consult with the resident's treatment team physician as soon as possible. The team physician must be informed of the emergency safety situation that required the resident to be restrained or placed in seclusion. Paragraph (b) of this section requires the facility to document in the resident's record the date and time the team physician was consulted.

We estimate that it will take approximately 15 minutes per situation, 282 annual responses per psychiatric residential treatment facility, or 26,508 hours (282 x 376 PRTFs x 0.25 hr) nationally to comply with the documentation and disclosure requirements of this section. This estimate is based on an assumption that approximately half of the situations will require that the facility staff separately notify the treatment team physician.

Section 483.366 Notification of parent(s) or legal guardian(s) and §483.374, Facility reporting, paragraph (b).

If the resident is a minor as defined in §483.352, §483.366 requires the facility to notify the parent(s) or legal guardian(s) of a resident who has been restrained or placed in seclusion as soon as possible after the initiation of each emergency safety intervention.

Paragraph (b) of §483.374 includes the requirement that the facility 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.

We estimate that it will take 30 minutes to notify a parent or guardian. The total annual burden will be 282 hours per psychiatric residential treatment facility and 106,032 hours nationally, based on the assumption that virtually all of the residents will be minors as defined in section 483.352.

We estimate that it will take 5 minutes for the psychiatric residential treatment facility to document in the residents' records that parents or legal guardians have been notified of an emergency safety intervention. The total annual burden will be 47 hours per psychiatric residential treatment facility and 17,672 hours nationally.

Paragraph (b) of §483.374 requires the facility to report serious occurrences involving a resident to both the State Medicaid Agency and, unless prohibited by State law, the State-designated Protection and Advocacy System. Paragraph (c) of §483.374 requires the facility to report the death of a resident to the CMS regional office. A 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.

We estimate that it will take 10 minutes to report and to document each occurrence (10 mins. X 47 incidents/mo. X 12 mos.) per facility for an annual burden of 94 hours. For 376 facilities this would equate to a national burden of 35,344 hours per year.

We estimate it will take 5 minutes to report each death to the CMS regional office and to document that report. We estimate fewer than 5 deaths annually for all 376 facilities. (5 mins. X 5 deaths annually would equate to a national burden of 25 minutes per year.)

Section 483.370 Post-intervention debriefings.

Paragraph (c) of this section requires that staff document in the resident's record that the debriefing sessions required by this section took place.

This documentation will take approximately 15 minutes per situation, or an annual burden of 141 hours per psychiatric residential treatment facility and 53,016 hours nationally.

Section 483.372 Medical treatment for injuries occurring as a result of an emergency safety situation.

Paragraph (b) of this section requires the psychiatric residential treatment facility to have affiliations or written transfer agreements in effect with one or more hospitals approved for participation under the Medicaid program that reasonably ensure that--

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

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

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

Paragraph (c) of this section requires that staff document in the resident's record all injuries that occur as a result of an emergency safety situation, including injuries to staff resulting from that intervention.
While these information collection requirements are subject to the PRA, we believe the burden associated with them is exempt as defined in 5 CFR 1320.3(b)(2). The time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities.

Section 483.374 Facility Reporting.

Paragraph (a) of this section requires each psychiatric residential treatment facility that provides inpatient psychiatric services to individuals under age 21 to attest, in writing, that the facility is in compliance with our standards governing the use of restraint and seclusion. This attestation must be signed by the facility director.

We estimate that it will take 8 hours per facility to be able to attest to compliance with the standards. This is a one-time burden. The national burden will be an estimated 376 facilities multiplied by 8, or 3,008 hours.

[NOTE: This requirement would only apply to new facilities since all of the 376 facilities have already met this requirement.]

Section 483.376 Education and training.

Paragraph (f) requires facilities to provide for assessments of staff education and training needs by requiring staff to demonstrate their competencies related to the use of emergency safety interventions on a semiannual basis. This section also provides for staff to demonstrate, on an annual basis, their competency in the use of cardiopulmonary resuscitation.

Paragraph (g) of this section requires the facility to document in the staff personnel records that the training required by section 483.376 was successfully completed.

While these information collection requirements are subject to the PRA, we believe the burden associated with them is exempt as defined in 5 CFR 1320.3(b)(2). The time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities.

Summary of Burden Estimates

Regulation Section(s)	Respondents	Responses (per Respondent)	Total Responses	Burden per Response (hours)	Total Annual Burden (hours)	Type of Burden
483.356 Disclose policy	376	95	35,720	.5	18,048	Third Party Disclosure
483.358(h) Orders	376	564	212,064	.5	106,032	Recordkeeping
483.358(i) Aggregate recordkeeping	376	564	212,064	15 min	53,016	Recordkeeping
483.360 Consultation	376	282	106,032	.25	26,508	Recordkeeping
483.366 Notification	376	564	212,064	.5	106,032	Third Party Disclosure
483.374(b) Report serious occurrence to State Medicaid Agency	376	564	212,064	10 min	35,344	Third Party Disclosure
483.374(b) Document notification	376	564	212,064	5 min	17,672	Recordkeeping
483.374(c) Report death to CMS	376	0.014	5	5 min	0.42	Reporting
483.370 Debriefings	376	564	212,064	.25	53,016	Recordkeeping
Total	376	--	1,414,141	--	415,668	

Type of Burden	**Annual Burden (hours)**
Recordkeeping	256,244
Third Party Disclosure	159,424
Reporting	0 (< 1 hr)
TOTAL	**415,668**

13. Capital Costs

There are no capital costs associated with the collection of this information.

14. Cost to Federal Government

There is no cost to the Federal Government with this information collection.

15. Program or Burden Changes

This is a reinstatement, without change, of a previously approved collection. The Office of Clinical Standards and Quality, Survey & Certification Group, uses the system currently known as CASPER to record facilities that meet requirements for Psychiatric Residential Treatment Facilities (PRTF). This was the system used to obtain the current number of PRTFs.

There are no program changes, however, burden estimates have been revised. For example, the number of facilities meeting the PRTF requirements at 42 CFR 440.160 has declined since 2008 (from 500 projected to 376 actual). This decline is reflected in the adjusted burden hours: 501,750 in 2008 to 415,668 in 2012. In addition to reinstating this collection, this ICR also seeks to correct a mathematical error regarding the number of total responses from 329,500 in 2008 to 1,414,141 in 2012.

16. Publication and Tabulation Dates

This collection of information is not intended for publication.

17. Expiration Date

There is no information collection form on which to display an expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

This collection does not employ statistical methods.