SUPPORTING STATEMENT A
Condition of Participation - Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities Providing Psychiatric Services to Individuals under Age 21 and Supporting Regulations
CMS-R-306, OMB 0938-0833

Background

Section 1902(a)(9)(A) of the Social Security Act (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 age 21 in hospital and non-hospital settings. Non-hospital settings, which we have defined as psychiatric residential treatment facilities treat individuals under age 21with psychiatric disorders whose illnesses require services on an inpatient basis under the direction of a physician in 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 requirements in this information collection request, as outlined below in section A.12, are intended to protect children and adolescents receiving services in these facilities from the dangers associated with the inappropriate use of restraint and seclusion. In this 2018/2018 information collection request, our requirements remain unchanged. However, we propose several burden adjustments and add an optional reporting worksheet.

A. Justification

1. <u>Need and Legal Basis</u>

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.

The Children's Health Act of 2000 (Pub. L. 106-310) signed by the President on October 17,

2000, imposes procedural reporting and training requirements regarding the use of restraints and involuntary seclusion in facilities, specifically including facilities that provide inpatient psychiatric services for children under the age of 21 as defined by sections 1905(a)(16) and (h) of the Act.

On January 22, 2001, CMS published in the Federal Register (66 FR 7148) an interim final rule which 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, CMS published in the Federal Register (66 FR 28110) 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 requirements under this information collection request assists States in monitoring the health and well-being of Medicaid-eligible individuals who receive care in private and public facilities. Specifically, these include facility requirements 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. In the case of a minor, the facility must also notify the parent(s) or legal guardian(s) of the resident involved in a serious occurrence.

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.

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 to the Joint Commission 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 by facilities 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, (42 CFR 483.374(b)), 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, (42 CFR 483.374(c)), 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.

Otherwise, there are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for

compatible confidential use; or

- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register Notice/Outside Consultation

The 60-day notice published in the Federal Register on June 19, 2018 (83 FR 28429). We did not receive any comments.

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

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates (hours and wages)

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the median hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

Hourly Wage Estimates

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Medical and Health Service Manager	11-9111	53.69	53.69	107.38
Mental Health and Substance Abuse Social Workers	21-1023	22.99	22.99	45.98
Registered Nurse	29-1141	35.36	35.36	70.72

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary

widely from study to study. We believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Collection of Information Requirements and Burden

(a) Section 441.151 General requirements.

Section 441.151(a)(4) 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 the requirement is subject to the PRA, we believe the associated burden 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.

(b) Section 483.356 Protection of residents.

Section 483.356(c), 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 December 11, 2018, there are currently 360 psychiatric residential treatment facilities[1]. We estimate an average resident length of stay to be 9 months whereby each facility would admit an average of 95 residents per year or 34,200 residents (360 facilities x 95 residents/year). On average we believe it will take 30 minutes at $45.98/hr for a Mental Health and Substance Abuse Social Worker to present the information to each incoming resident and the parent(s) or guardian(s), and to obtain and file the acknowledgment.

In aggregate we estimate an annual burden of **17,100 hours** (34,200 residents x 0.5 hr/resident) at a cost of **$786,258** (17,100 hr x $45.98/hr).

While the disclosure is an ongoing requirement, the development of the policy statement is a one-time 8-hour requirement that has been met by existing facilities. Nevertheless, we estimate 14 new facilities would be subject to this requirement per year.

We expect that a Medical and Health Service Manager at $107.38/hr would be responsible for developing the policy statement. In this regard we estimate an annual burden of **112 hours** (14 facilities x 8 hr/facility) at a cost of **$12,026.56** (112 hr x $107.38/hr).

1 https://qcor.cms.gov/PRTF_wizard.jsp?which=13&report=active.jsp

(c) Section 483.358 Orders for the use of restraint or seclusion.

In accordance with §483.358,(d) 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 requirement is subject to the PRA, we believe the associated burden is exempt under 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

In accordance with §483.358(h), 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.

We estimate an average of 47 situations per month (564 per year) per psychiatric residential treatment facility where restraint or seclusion is used. In total we estimate 203,040 situations (47 situations/month x 12 months x 360 facilities).

We expect it will take 30 minutes at $70.72/hr for a Registered Nurse to comply with the documentation requirements. In aggregate we estimate an annual burden of **101,520 hours** (203,040 situations x 0.5 hr/response) at a cost of **$7,179,494.40** (101,520 hr x $70.72/hr).

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

We expect it would take 15 minutes at $70.72/hr for a Registered Nurse to document each emergency safety situation. In aggregate we estimate an annual burden of **50,760 hours** (203,040 situations x 0.25 hr/response) at a cost of **$3,589,747.20** (50,760 hr x $70.72/hr).

In §483.358(j), 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 requirement is subject to the PRA, we believe the burden is exempt under 5 CFR 1320.3(b)(2) since the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

(d) 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 **25,380 hours** (282 x 360 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 (564/2) will require that the facility staff separately notify the treatment team physician.

The hourly adjusted rate for a Registered Nurse to separately notify the treatment team physician is estimated to be $70.72/hr. Multiplying the total annual burden of 25,380 hours by the hourly wage yields an associated equivalent cost of about **$1,794,873.60** for all notifications.

(e) Section 483.366 Notification of parent(s) or legal guardian(s).

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 §483.366 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. As noted above, we estimate 564 situations per year per facility.

We estimate that it will take 30 minutes to notify a parent or guardian and document the resident’s records of the notification. The total annual burden will be 282 hours per psychiatric residential treatment facility (564 situations x .5 hr) and **101,520 hours** nationally, (282 x 360) based on the assumption that virtually all of the residents will be minors as defined in section 483.352.

The hourly rate for a Registered Nurse to notify a parent or guardian of a resident who has been restrained or placed in seclusion and document the resident’s records of the notification is estimated to be $70.72/hr. Multiplying the total annual burden of 101,520 by the hourly wage yields an associated cost of about **$7,179,494.40**.

(f) 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 50,760 hours nationally.

The hourly adjusted rate for a Registered Nurse to document the resident's record that a debriefing session took place is estimated to be $70.72/hr. Multiplying the total annual burden of **50,760 hours** by the hourly wage yields an associated equivalent cost of about **$3,589,747.20**.

(g) 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--

(1) 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.

(h) 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 previous national burden was 376 facilities multiplied by 8, or 3,008 hours. As we estimate there are 14 new facilities included in this summary, the national burden is 14 facilities multiplied by 8 or 112 hours to attest to compliance with the standards.

The hourly adjusted rate for a Medical and Health Service Manager responsible for attesting to compliance with CMS standards is $107.38/hr. Multiplying the total burden of **112 hours** by the hourly wage yields an associated cost of about **$12,026.56**.

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.

We estimate that it will take 10 minutes to report and to document each occurrence (10 min x 47 incidents/month x 12 months/year) per facility for an annual burden of 94 hours. For 360 facilities this would equate to a national burden of **33,840 hours** per year.

The hourly adjusted rate for a Medical and Health Service Manager responsible for reporting serious occurrences involving a resident is $107.38/hr. Multiplying the total burden of 33,840 hours by the hourly wage yields an associated cost of about **$3,633,739.20**.

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 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 360 facilities. Five (5) minutes x 5 deaths annually would equate to a national burden of 25 minutes per year.

The hourly adjusted rate for a Medical and Health Service Manager responsible for notifying the CMS regional office of a death a documenting the report is $107.38/hr. Multiplying the total burden of **0.42 hours** by the hourly wage yields an associated cost of about **$45.10**.

(i) 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	Total Responses	Burden per Response	Total Annual Burden (hours)	Hourly Labor cost of Reporting ($/hr)	Total Labor Cost of Reporting ($)
483.374(a) Facility Reporting Attestation	14	14	8 hr	112	107.38	12,027
483.374(b) Report Serious Occurrence to State Medicaid Agency	360	203,040 (360 x 564)	10 min	33,840	107.38	3,633,739
483.374(c) Report death to CMS	5	5	5 min	0.42 (25 min)	107.38	45
Subtotal (Reporting)	*360*	*203,059*	*Varies*	*33,952.42*	*107.38*	*3,645,811*
483.356 Disclose Policy	360	34,200 (360 x 95)	30 min	17,100	45.98	786,258
483.356 Develop Policy Statement	14	14	8 hr	112	107.38	12,027
Subtotal (Third Party Disclosure)	*360*	*34,214*	*Varies*	*17,212*	*Varies*	*3,645,811*
483.358(h) Orders	360	203,040 (360 x 564)	30 min	101,520	70.72	7,179,494
483.358(i) Aggregate Recordkeeping	360	203,040 (360 x 564)	15 min	50,760	70.72	3,589,747
483.360(a) Consultation with Team Physician	360	101,520 (360 x 282)	15 min	25,380	70.72	1,794,874
483.366(b) Notification of Parents/guardians	360	203,040 (360 x 564)	30 min	101,520	70.72	7,179,494
483.370(c) Debriefings	360	203,040 (360 x 564)	15 min	50,760	70.72	3,589,747
483.374(b) Document Notification	360	203,040 (360 x 564)	10 min	33,840	107.38	3,633,739
Subtotal (Recordkeeping)	*360*	*1,116,720*	*Varies*	*363,780*	*Varies*	*26,967,095*
Total	**360**	**1,353,993**	**Varies**	**414,944**	**Varies**	**34,258,717**

Collection of Information Instruments and Instruction/Guidance Documents

The worksheet is an internal CMS form that is not required by State Medicaid Agencies. State Medicaid agencies have used that form from time to time when reporting to the CMS Regional

Office.

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

While we have not revised our per response burden estimates, we have adjusted the number of respondents from 390 to 360. The result adjusts our total time estimate by minus 34,665 hours. The number of respondents for §§483.56(c), 483.374(a), and 483.374(c) remains unchanged as does their respective total time figures of 112 hr, 112, hr and 0.42 hr.

The adjustment is based on data from the CMS Certification and Survey Provider Enhanced Reports (CASPER) system. As of December 11, 2018, there are currently 360 psychiatric residential treatment facilities[2].

We also added a reporting worksheet which is an internal CMS form that is not required by State Medicaid Agencies. State Medicaid agencies have used that form from time to time when reporting to the CMS Regional Office. The per response reporting burden is currently approved by OMB and remains unchanged.

Regulation Section(s)	Respondents			Hours (Total)		
	Currently Approved	**Proposed**	**Difference**	**Currently Approved**	**Proposed**	**Difference**
483.356 Disclose Policy	390	360	(30)	18,720	17,100	(1,620)
483.358(h) Orders	390	360	(30)	109,980	101,520	(8,460)
483.358(i) Aggregate Recordkeeping	390	360	(30)	54,990	50,760	(4,230)
483.360(a) Consultation with Team Physician	390	360	(30)	27,495	25,380	(2,115)
483.366(b) Notification of Parents/guardians	390	360	(30)	109,890	101,520	(8,370)
483.370(c) Debriefings	390	360	(30)	54,990	50,760	(4,230)
483.374(b) Report Serious Occurrence to State Medicaid	390	360	(30)	36,660	33,840	(2,820)

2 https://qcor.cms.gov/PRTF_wizard.jsp?which=13&report=active.jsp

Regulation Section(s)	Respondents			Hours (Total)		
	Currently Approved	Proposed	Difference	Currently Approved	Proposed	Difference
Agency						
483.374(b) Document Notification	390	360	(30)	36,660	33,840	(2,820)
Total	**390**	**360**	**(30)**	**449,385**	**414,720**	**(34,665)**

The ROCIS burden table has been corrected by reassigning requirements under their respective collection type.

16. Publication and Tabulation Dates

This collection of information is not intended for publication.

17. Expiration Date

The expiration date is displayed.

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.