

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 441 and 483

[HCFA-2065-IFC]

RIN 0938-AJ96

Medicaid Program; Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities Providing Psychiatric Services to Individuals Under Age 21

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period establishes a definition of a "psychiatric residential treatment facility" that is not a hospital and that may furnish covered Medicaid inpatient psychiatric services for individuals under age 21. This rule also sets forth a Condition of Participation (CoP) that psychiatric residential treatment facilities that are not hospitals must meet to provide, or to continue to provide, the Medicaid inpatient psychiatric services benefit to individuals under age 21. Specifically, this rule establishes standards for the use of restraint or seclusion that psychiatric residential treatment facilities must have in place to protect the health and safety of residents. This CoP acknowledges a resident's right to be free from restraint or seclusion except in emergency safety situations. We are requiring psychiatric residential treatment facilities to notify a resident (and, in the case of a minor, his or her parent(s) or legal guardian(s)) of the facility's policy regarding the use of restraint or seclusion during an emergency safety situation that occurs while the resident is in the program. We believe these added requirements will protect residents against the inappropriate use of restraint or seclusion.

DATES: *Effective date:* These regulations are effective on March 23, 2001.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on March 23, 2001.

ADDRESSES: Mail written comments (one original and three copies) to the following address ONLY: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-2065-IFC, P.O. Box 8010, Baltimore, MD 21244-8010.

If you prefer, you may deliver your written comments (one original and three copies) by courier to one of the following addresses: Room 443-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or C5-15-03, Central Building, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments mailed to those addresses may be delayed and could be considered late.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-2065-IFC.

Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 443-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (Phone (202) 690-7890).

For comments that relate to information collection requirements, mail a copy of comments to: Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room N2-14-26, 7500 Security Boulevard, Baltimore, MD 21244-1850, Attn: Julie Brown, HCFA-2065-IFC.

FOR FURTHER INFORMATION CONTACT: Mary Kay Mullen, (410)786-5480.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1902(a)(9)(A) of the Social Security Act (the 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. Section 1905(h) of the Act defines the term "inpatient psychiatric hospital services for individuals under age 21" as inpatient services that are provided in an institution (or distinct part thereof) that is a psychiatric hospital or in another inpatient setting that the Secretary has specified in regulations. In this interim final rule, we are defining psychiatric residential treatment facilities as an inpatient setting in conformity with the definition of an institution as set forth in section 1905(h).

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 nonhospital settings. Nonhospital settings, which we are defining as psychiatric residential treatment facilities (facilities), are rapidly replacing hospitals in treating children and adolescents with psychiatric disorders. These facilities are generally a less restrictive alternative to a hospital for treating children and adolescents whose illnesses are less acute but who still require a residential environment.

On November 17, 1994, we published in the **Federal Register** (56 FR 59624) proposed regulations to establish standards for nonhospital 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.

We, as well as the Congress, have grown increasingly concerned 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. 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. 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.

Advocates for persons with mental illness as well as the media have raised the public's awareness of restraint and seclusion practices that can lead to serious injury and death. The *Hartford Courant* (*Courant*), a Connecticut newspaper, published a series of articles in October 1998 citing the results of a

50-state survey that confirmed 142 deaths, that occurred during the previous decade, while or shortly after a patient was restrained or secluded. The first of a series of articles entitled "A Nationwide Pattern of Death," was published October 11, 1998. The survey focused on mental health and mental retardation facilities and group homes nationwide. According to a statistical estimate commissioned by the *Courant* that was conducted by the Harvard Center for Risk Analysis, between 50 and 150 deaths related to the use of restraint or seclusion occur every year across the country. The article further stated that of the 142 restraint-related deaths confirmed by the *Courant's* investigation, ages could be confirmed in 114 cases, and that more than 26 percent of those were children—nearly twice the proportion they represent in mental health institutions.

In 1999, at the request of the Congress, the General Accounting Office (GAO) conducted a study that focused on individuals receiving services in mental health and mental retardation facilities and group homes nationwide that receive public funding, primarily from the Medicare and Medicaid programs. Some objectives of the study were to determine the dangers of restraint and seclusion, the extent to which restraint and seclusion are used in inpatient and residential treatment facilities for individuals with mental illness or mental retardation, and the number of related injuries and deaths from their use. To gain at least a partial indication of the scope of the problem, the GAO obtained data on the number of deaths related to restraint or seclusion investigated by the Protection and Advocacy agencies in all 50 states and the District of Columbia in fiscal year 1998. On the basis of the partial information available from the 51 agencies, the GAO identified 24 deaths associated with restraint or seclusion during fiscal year 1998.

In September of 1999, the GAO issued a report titled "Improper Restraint or Seclusion Use Places People at Risk" (GAO/HEHS-99-176), which concluded that the 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 facility. In addition, according to the report, most facilities are not even required to report these data to oversight agencies. The report stated that because reporting

is so fragmentary, there may be many more deaths related to the use of restraint or seclusion than are being reported.

The *Courant* series and the GAO report underscore our concern for the safety and welfare of children and adolescents when restraints or seclusion are employed in residential treatment facilities. We have therefore developed standards that describe the conditions under which restraint or seclusion can be used; that set an upper limit on the permissible length of time for each instance of restraint or seclusion use; that require education and training of staff, including the safe use of restraint and the safe use of seclusion; that require staff to directly monitor residents who are restrained or secluded for the entire duration of the procedure; and that prohibit the simultaneous use of restraints and seclusion.

On July 2, 1999, we published in the **Federal Register** an interim final rule that addressed, in part, the use of restraint and seclusion in hospitals, including psychiatric hospitals, entitled "Medicare and Medicaid Programs; Hospital Conditions of Participation; Patients' Rights" (64 FR 36070). We conducted substantial academic research on the issue of restraint and seclusion, which was discussed in the referenced hospital interim final rule. Although the research primarily involved elderly patients, its findings, we believe, are also relevant to individuals under age 21. As we said there: "Research indicates that the potential for injury or harm with the use of restraint is a reality. In a 1989 article published in the *Journal of the American Geriatrics Society*, Evans and Strumpf pointed to an association between the use of physical restraint and death during hospitalization (Evans, LK and Strumpf, NE: Tying down the elderly: A review of the literature on physical restraint. *J Am Geriatr Soc* (1989) 37:65-74; also see Robbins, LJ, Boyko E, Lane, J, et al.: Binding the elderly: A prospective study of the use of mechanical restraint in an acute care hospital. *J Am Geriatr Soc* (1987) 35:290; Frengley, JD and Mion, LC: Incidence of physical restraints on acute general medical wards. *J Am Geriatr Soc* (1986) 34:565; Strumpf, NE and Evans, LK: Physical restraint of the hospitalized elderly: Perceptions of patients and nurses. *Nursing Research* (1998) 37:132.) The FDA estimates that at least 100 deaths from the improper use of restraints may occur annually. Mion et al. further noted that "Some evidence exists that the use of physical restraints is not a benign practice and is associated with adverse effects, such as

longer length of hospitalization, higher mortality rates, higher rates of complications, and negative patient reactions. Physical restraints have a detrimental effect on the psychosocial well-being of the patient" (see Mion et al.: A further exploration of the use of physical restraints in hospitalized patients. *J Am Geriatr Soc* (1989) 37:955; Schafer, A: Restraints and the elderly: When safety and autonomy conflict. *Can Med Assoc J* (1985) 132:1257-1260.)"

"Research findings on the impact of restraints use have lead to research on and development of alternative methods for handling the behaviors and symptoms that historically prompted the application of restraint. However, various studies provide evidence that restraint is still being used when alternate solutions are available (see Donat, DC: Impact of a mandatory behavior consultation on seclusion/restraint utilization in psychiatric hospitals. *J Behav Ther Exp Psychiatry* (1998 March) 29:1, 13-9; Dunbar, J: Making restraint-free care work. *Provider* (1997 May) 75-76, 79; and Moss RJ: Ethics of mechanical restraints. *Hasting Center Report* (1991 Jan-Feb) 21 (1):22-25.)"

In the preamble of the July 1999 hospital interim final rule, we asked for comments on whether we should apply the hospital behavioral health standards on the use of restraint and seclusion to psychiatric residential treatment facilities that provide inpatient psychiatric services to individuals under age 21, or whether more stringent standards were warranted. Consumer advocacy groups that commented on extending the restraint and seclusion requirements to other types of providers and settings generally agreed that more stringent regulations should be applied with respect to the treatment of children. Their opinion was that the restraint of children and adolescents in these settings presents special hazards and concerns. Those comments will be addressed more specifically in the hospital final rule. Additionally, the 1999 GAO report described a study sponsored by the Center for Mental Health Services which indicated that there are higher restraint rates for children, including one State in which children in State-run facilities were restrained four times more frequently than adults. This report also noted that children are smaller and weaker than adults, so staff who are used to overpower adults may apply too much pressure or force when restraining children. For all of these reasons, HCFA has included standards in this rule that provide greater protection than those in

existence or required by the Children's Health Act of 2000.

Generally, the requirements set forth in this rule governing the use of restraint and seclusion are consistent with both the November 1994 proposed rule and the July 1999 hospital interim final rule. Moreover, this rule also meets the specific requirements of section 3207 of the Children's Health Act of 2000 (Pub. L. 106-310) which requires that health care facilities receiving support in any form from any program supported in whole or in part with funds appropriated to any Federal department or agency shall protect and promote the rights of each resident of the facility, including the right to be free from any restraints or involuntary seclusion imposed for purposes of discipline or convenience. Specifically, section 591(c) of the Children's Health Act permits the Secretary to issue regulations that afford residents greater protections regarding restraint and seclusion than the standards published in the new law. Consistent with this section, this rule provides greater protections than those required in section 3207.

Psychiatric residential treatment facilities are fast replacing hospitals in providing long-term mental health services to children and adolescents, a highly vulnerable population. The dangers associated with the inappropriate use of restraint and seclusion, especially with this population were well documented in the GAO Report and the *Courant* series. According to the GAO Report, children are subjected to restraint and seclusion at higher rates than adults and are at greater risk of injury. Based on the mounting evidence of harm that can result from the use of restraint and seclusion, we are being more prescriptive in the way our restraint and seclusion standards are applied in psychiatric residential treatment facilities.

II. Provisions of the Interim Final Rule Effect of This Rule on the Survey and Certification Requirements

This interim final rule implements only one of the conditions of participation (CoPs) set forth in our November 1994 proposed rule. We are not implementing the remainder of the CoPs in that proposed rule at this time because many of the comments we received on that proposed rule are still under evaluation. We plan to address the remainder of the CoPs in our November 1994 proposed rule in a separate rule in the future. As discussed below, we are moving forward with this CoP because evidence indicates a

pressing need for the promulgation and enforcement of restraint and seclusion rules for psychiatric residential treatment facilities.

Requiring psychiatric residential treatment facilities to meet these CoPs will require us to develop additional survey protocols and implementing guidelines to enforce these new requirements. We will solicit public comment on these survey protocols. Until such protocols are issued, we are requiring each psychiatric residential treatment facility that provides inpatient psychiatric services to individuals under age 21 under a State plan to attest, in writing, that the facility is in compliance with the standards set forth in this rule governing the use of restraint and seclusion. This attestation must be signed by the facility director. In addition, we are requiring the facility to provide the State Medicaid agency with its attestation of compliance. Since the facility will need time to implement these restraint and seclusion standards before it can come into compliance, we are allowing the facility 120 days from the effective date of this interim final rule to provide the State Medicaid agency with its attestation of compliance.

We will work with the States to develop a process for sampling psychiatric residential treatment facilities to validate their attestations of compliance with the restraint and seclusion standards.

This interim final rule establishes a definition of a psychiatric residential treatment facility as a facility other than a hospital that provides inpatient psychiatric services and sets forth a CoP entitled "Use of Restraint or Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services for Individuals Under Age 21." This CoP is in addition to the existing regulatory requirements for these facilities in 42 CFR 441.151 through 441.182, which specify requirements applicable if a State plan provides for inpatient psychiatric services to individuals under age 21.

Section 441.151 General Requirements

This regulation amends § 441.151 by redesignating existing paragraphs, by adding explicit reference to residential treatment facilities, and by adding a new paragraph (b) to establish a CoP in part 483, subpart G, that facilities must meet in order to provide these services.

Section 483.352 Definitions

We have included in this section, definitions of terms as they apply to the standards in this rule governing the use

of restraint and seclusion in psychiatric residential treatment facilities.

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

Section 483.354 General Requirements for Psychiatric Residential Treatment Facilities

This section clarifies that in addition to the requirements specified in this rule, psychiatric residential treatment facilities must meet the requirements in §§ 441.151 through 441.182 of this chapter.

Section 483.356 Protection of Residents

The purpose of this CoP is to protect residents in psychiatric residential treatment facilities from the inappropriate use of restraint or seclusion by addressing the right of each resident to be free from restraint or seclusion, in any form, imposed as a means of coercion, discipline, convenience, or retaliation.

An example of the inappropriate use of seclusion or restraint for purposes of coercion would be the use of seclusion or restraint with a resident whose behavior would not require its use, and who is not endangering others, but where seclusion or restraint is being used until the resident takes prescribed medications or attends a required group therapy session. We are seeking public comment on the use of the term coercion.

The CoP provides for the use of restraint or seclusion only in emergency safety situations to ensure the safety of the resident or others, and only until the emergency safety situation ends. An order for restraint or seclusion cannot be issued as a standing order. We also are prohibiting the simultaneous use of restraint and seclusion in psychiatric residential treatment facilities. Combining a mechanical restraint intervention with isolation (seclusion) is extremely restrictive and dangerous.

In § 483.356(c) we are requiring each facility to inform both the resident and, in the case of a minor, his or her parent(s) or legal guardian(s) of its policy regarding the use of restraint or seclusion. To comply with Executive Order 13166 (Improving Access to

Services for Persons with Limited English Proficiency) which was issued on August 11, 2000, each facility is required to 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 that, when necessary, interpreters or translators are provided. We believe that the resident (and, in the case of a minor, the parent(s) or legal guardian(s)) must be informed of the facility's restraint and seclusion policy at the time of admission to foster the selection of a provider best suited to meet the physical and mental health needs of the resident. We are also requiring the facility to provide a copy of the facility's policy to the resident, and if a minor, a copy to both the resident and the resident's parent(s) or legal guardian(s). The facility's policy must provide the information needed for contacting the State Protection and Advocacy Organization.

Section 483.358 Orders for the Use of Restraint or Seclusion

Under this new standard, restraint or seclusion may be imposed only in emergency safety situations.

This standard provides that only a board-certified psychiatrist, or a licensed physician with specialized training and experience in diagnosing and treating mental disorders, may order restraint or seclusion in emergency safety situations. This person must be the resident's treatment team physician, if available. When he or she is not available, the physician covering for the treatment team physician may order restraint or seclusion. The covering physician must meet these same requirements for training and experience.

We are limiting the authority to order the use of restraint and seclusion in psychiatric residential treatment facilities to a board-certified psychiatrist or a licensed physician with specialized training and experience in diagnosing and treating mental disorders. Our requirement that only a board-certified psychiatrist or a licensed physician may order restraint or seclusion is consistent with existing physician admission and certification of need for services requirements applicable if a State provides inpatient psychiatric services to individuals under age 21 in psychiatric facilities. Regulatory requirements at 42 CFR part 441, subpart D and part 456, subpart D require that inpatient psychiatric services for individuals under age 21 be provided under the direction of a physician, and that a physician must

certify, in writing, that inpatient psychiatric services are necessary in the setting in which they will be provided.

Any order for restraint or seclusion must be the least restrictive intervention that is most likely to be effective in resolving the emergency safety situation based on consultation with staff and must be limited to no longer than the duration of the emergency safety situation. If the physician is not present in the facility to order the use of restraint or seclusion, we are requiring in § 483.358(d) that a registered nurse obtain the physician's verbal order at the time the emergency safety intervention is initiated by staff. The physician's verbal order must be followed with the physician's signature verifying the verbal order. The ordering physician must be available to staff at least by phone for the duration of the restraint or seclusion to ensure the resident's safety.

The time limits for restraint or seclusion orders in this rule are consistent with the July 1999 hospital interim final rule: no more than 4 hours for residents ages 18 to 21, 2 hours for residents ages 9 to 17, and 1 hour for residents under age 9. We are soliciting comments on these time limits.

In § 483.358, we are also requiring that within 1 hour of the initiation of an emergency safety intervention, a face-to-face assessment of the physical and psychological well-being of the resident be conducted. We believe this assessment is necessary to ensure the safety of the resident during and immediately after he or she is restrained or secluded. We believe that requiring that this assessment be performed by a physician would be unrealistic because unlike hospitals, a psychiatric residential treatment facility may not have a physician present 24 hours a day. Therefore, when a physician is not present, we are allowing a clinically qualified registered nurse trained in the use of emergency safety interventions to perform the face-to-face assessment. Both the face-to-face assessment and the restraint or seclusion order must be documented in the resident's record by staff involved in the emergency safety intervention before the end of their shifts. The ordering physician must sign the order as soon as possible.

Section 483.360 Consultation With Treatment Team Physician

If the physician who orders 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. We believe it is important that the team physician be made aware of

any circumstances that have disrupted the physical or psychological well-being of the resident as soon as possible so that the team physician can evaluate the situation(s) that required the resident to be restrained or secluded and make appropriate modifications to the resident's plan of treatment. We are requiring documentation in the resident's record that the treatment team physician was contacted.

Section 483.362 Monitoring of the Resident in and Immediately After Restraint

We are requiring that clinical staff trained in the use of emergency safety interventions be physically present, continually assessing and monitoring the resident in restraint. If the emergency safety situation continues beyond the time limits of the order, a registered nurse must immediately contact the ordering physician in order to receive further instructions. A physician or registered nurse must evaluate the resident immediately after the restraint is removed. We believe these requirements will further ensure resident safety.

Section 483.364 Monitoring of the Resident in and Immediately After Seclusion

We are requiring a resident in seclusion to be continually monitored and assessed by clinical staff, trained in the use of emergency safety interventions and that the staff monitoring the resident must be physically present in or immediately outside the seclusion room to ensure the safety of the resident. Video monitoring of the resident in seclusion will not meet this requirement because such monitoring cannot determine if a resident is experiencing a medical emergency such as cardiac arrest or asphyxiation.

This standard also specifies the characteristics of a room used for seclusion, including the requirements that the interior of the seclusion room be fully visible to staff and be free of any potentially hazardous conditions. We also are requiring that a physician or registered nurse evaluate the resident immediately after the resident is removed from seclusion. As stated in the discussion of § 483.262, we believe these requirements will ensure resident safety.

Section 483.366 Notification of Parent(s) or Legal Guardian(s)

We are requiring the facility to notify the parent(s) or legal guardian(s) whenever a resident who is a minor (as defined in this subpart) is restrained or

secluded. Notification must be made as soon as possible after the initiation of each emergency safety intervention and must be documented in the resident's record.

Section 483.368 Application of Time Out

We have defined "time out" in § 483.352 "Definitions" to clarify that it is not a form of seclusion, because the resident in time out is not physically prevented from leaving the time out area. The regulation also clarifies that time out can take place away from other residents (exclusionary) or in the area of activity or in the presence of other residents (inclusionary). This section further requires staff to monitor the resident while he or she is in time out. We considered establishing time limits for time out, but because age, maturity level, health status, and other factors must be considered, we believe that the duration of time out should be based on professional judgement. We welcome comments on this issue.

Section 483.370 Postintervention Debriefings

In order to ensure the safety of resident's and others, we believe it is critical that the facility begin to quickly assess the circumstances that warranted the use of restraint or seclusion and to identify alternatives to reduce or eliminate their use. Therefore, we are requiring that within 24 hours after a resident has been restrained or secluded, staff involved in the emergency safety intervention and the resident, participate in a face-to-face discussion. This discussion can also include other staff and the resident's parent(s) or legal guardian(s) when it is deemed appropriate by the facility. As stated earlier, the facility must ensure that such discussions are conducted in a language that is understood by the resident and the resident's parent(s) or legal guardian(s). The discussion will provide both the resident and staff involved an opportunity to discuss the circumstances that resulted in the use of restraint or seclusion and strategies that all parties could employ to prevent the need for restraint or seclusion. However, we recognize that there may be clinical reasons why it may not be appropriate for a particular staff person involved in the emergency safety intervention to be part of the debriefing. If the presence of a particular staff person jeopardizes the well-being of the resident, it may not be advisable to include that staff person in a debriefing session. Therefore, this rule provides an exception to the requirement for those situations when the presence of a particular staff person

jeopardizes the well-being of the resident.

We also are requiring a separate debriefing of staff involved in the emergency safety intervention, and a review by appropriate supervisory and administrative staff of the situation that required the use of restraint or seclusion. However, we are not requiring that this debriefing be face-to-face.

We believe staff debriefings may identify areas requiring modification of administrative policy and procedures pertaining to the use of restraint or seclusion, and may serve to reduce use of restraint or seclusion. We believe the debriefing is critical to ensuring the safety of the resident and others and should take place within 24 hours after the use of restraint or seclusion. We are specifically requesting comments regarding the 24 hour requirement for debriefings involving staff and a resident, as well as debriefings between staff involved in an intervention and appropriate administrative and supervisory staff.

Section 483.372 Medical Treatment for Injuries Resulting from an Emergency Safety Intervention

This standard requires qualified medical personnel to immediately provide medical treatment to a resident who is injured during restraint or seclusion and to document these injuries in the resident's record. Injuries sustained by staff during the restraint or seclusion of a resident must also be documented in the resident's record. We believe this information will be important in assisting the facility in identifying measures to improve the safety of its staff through modifications of existing policies and procedures in the safe use of restraint and seclusion, and modification of training programs. We are also requiring staff involved in an emergency safety intervention that results in injury to the resident or staff to meet with supervisory staff to evaluate the circumstances that caused the injury and develop a plan to prevent future injuries.

In our November 1994 proposed rule, we proposed a separate condition of participation in § 483.220 entitled "Health Services," which would require each facility to have written transfer agreement(s) in effect with one or more Medicaid-approved hospitals that reasonably ensures a resident will be transferred in a timely manner from the facility to the hospital when transfer is medically necessary for medical care or acute psychiatric care. In addition, we proposed to require that medical and other information needed for care of the

resident be exchanged between the institutions, and that medical care be available to each resident 24 hours a day as may be necessary.

We received one comment on the transfer agreement requirement stating that it would be difficult to meet this requirement because most facilities are not affiliated with a hospital and that admission criteria and placement authority rests with each county and insurance provider. We considered the commenter's rationale but believe these agreements are necessary because the use of restraint or seclusion may place a resident at risk for an acute medical crisis. Therefore, we are incorporating in this CoP the requirement that each facility have written transfer agreement(s) or affiliations in place.

Section 483.374 Facility Reporting

According to the GAO report, reporting requirements play a central role in reducing restraint use and improving the safety of individuals in treatment settings. The report further states that in addition to tracking restraint rates, reporting of deaths or other significant events to an independent agency can contribute to improved safety for individuals in treatment settings. The GAO report specifically recommended that we mandate that any hospital or residential facility that treats persons with mental illness or mental retardation, as a requirement for receiving Medicare and Medicaid funds, report promptly to the State licensing body and the appropriate State Protection and Advocacy (P&A) system, all patient deaths and serious injuries among persons with mental illness or mental retardation, and to indicate whether restraint or seclusion was used during or immediately prior to the death or injury.

This interim final rule requires each facility to report a resident's death, any serious injury to a resident as defined in this subpart, and a resident's suicide attempt to the State Medicaid agency and, unless prohibited by State-law, the State-designated P&A system. These serious occurrences involving a resident must be reported to the State Medicaid agency and the State-designated P&A system no later than the close of business the next business day following the occurrence. We are also requiring each facility to document all serious occurrences in the resident's record. In the case of a minor, we are requiring the facility to notify (within 24 hours of the occurrence) the resident's parent(s) or legal guardian(s) in order to provide the parent(s) or legal guardian(s) the opportunity to participate in decisions that may have to

be made regarding the resident. We are requiring staff to document in the resident's record that these contacts were made. It should be noted that the facility reporting requirements in this rule exceed the minimum requirements for facility reporting in section 3207 of the Children's Health Act of 2000.

Regulations titled "Substance Abuse and Mental Health Services Administration; Requirements Applicable to Protection and Advocacy of Individuals with Mental Illness" published by the Department of Health and Human Services on October 15, 1997 (62 FR 53548) grant the P&A system the authority to protect and advocate for the rights of individuals with mental illness and to investigate reports of abuse and neglect in residential facilities that care for and treat individuals with mental illness. The P&As may have access to public and private facilities, residents, and clients, and to facilities' records of individuals with mental illness for the specific purpose of conducting independent investigations of incidents of abuse and neglect.

Under separate guidance or rulemaking (as appropriate), we will direct the State Medicaid agency to report serious occurrences involving a resident of a psychiatric residential treatment facility to the State survey agency. Section 1902(a)(33)(B) of the Act requires States to survey institutional providers, to certify that they meet our regulations for participation in the Medicaid program under the State plan.

Section 483.376 Education and Training

We are requiring the facility to provide ongoing education and training for staff including training in the safe and appropriate use of restraint and seclusion, as well as alternative nonintrusive behavior modification techniques. We also are requiring that staff be certified in the use of cardiopulmonary resuscitation. This training must be performed by individuals qualified by education, training, and experience. Staff must be able to successfully demonstrate, in practice, all techniques learned related to emergency safety interventions. Staff personnel records must document that this training was successfully completed. Staff must demonstrate their competencies on a semiannual basis. Each facility must make all training programs and materials available for review by HCFA, the State Medicaid agency, and the State survey agency. It should be noted that the education and training requirements in this rule

exceed the minimum requirements for education and training in section 3207 of the Children's Health Act of 2000.

We believe this training is essential because restraint and seclusion can be dangerous to both the individual being restrained or secluded and to staff applying restraint or seclusion. Restraining individuals can involve physical struggle, pressure on the chest, or other interruptions in breathing. Having staff trained in alternative techniques to avoid restraint use is important, but staff should also be trained in the proper application and removal of restraints and in how to monitor individuals in restraint or seclusion. The GAO report stated that the Joint Commission on Accreditation of Health Care Facilities (JCAHO) had reviewed 20 restraint-related deaths and found that in 40 percent, the cause of death was asphyxiation, while strangulation, cardiac arrest, or fire had caused the remainder. The report recommended that we require any inpatient or residential facility that treats persons with mental illness to ensure that staff regularly receives training and refresher courses in alternate methods to handle agitated or potentially violent patients and document their receipt of training as a requirement for receiving Medicare and Medicaid funds.

III. Response to Comments on November 1994 Proposed Standards Governing Restraints and Seclusion

In response to our November 1994 proposed rule, we received the following comments, which specifically addressed our proposed standards for restraints. Most of the commenters suggested that our standards address seclusion as well as restraints. We agree with the commenters and have included in this interim final rule standards addressing the use of both seclusion and restraint.

One commenter stated that we should prohibit the use of any type of restraint, including seclusion and time-out rooms. Six commenters stated we should prohibit restraints because they are not therapeutic and if they are allowed for one purpose, they cannot be monitored for other uses.

While we recognize that serious consequences can result from the inappropriate use of restraint or seclusion as discussed previously, we believe that restraint or seclusion used only in an emergency safety situation to ensure the safety of the resident or others is permissible when staff have been properly trained in the safe use of such interventions. Therefore, we have rejected these comments because we

believe that the type of intervention used to ensure the safety of a resident or others during an emergency safety situation should be the decision of the professionals involved in the situation.

Three commenters contended that restraints/seclusion should not be included in the plan of care and should be used only when an individual is a danger to himself or others, or is a serious disruption to the therapeutic environment. They also stated that restraints should be used only as long as physical danger continues. We generally agree with these comments, and as discussed previously, have limited the use of restraint or seclusion to emergency safety situations to ensure the safety of the resident or others in the facility. We are permitting the use of restraint or seclusion only until the emergency safety situation has ceased and the safety of the resident or safety of others can be ensured, even if the restraint or seclusion order has not expired. We are specifically prohibiting the use of standing orders for restraint or seclusion in these facilities.

Two commenters suggested deleting "involuntary" before seclusion in the proposed "freedom from abuse standard" and suggested we include seclusion under our "restraint" standard. We are not including a standard entitled "freedom from abuse" in this rule. Rather, we have separately defined restraint, seclusion, and time out in this rule. We believe our definitions of seclusion and time out sufficiently address the difference between "voluntary" and "involuntary seclusion" and therefore address the commenter's concerns.

Seven commenters stated that we should allow seclusion because it is less intrusive and restrictive than restraints, but that we should specify procedures governing its use, including authorization by the attending physician within a brief period before it is imposed, observation at frequent intervals and access to meals and toilet. These commenters stated that parents should be notified within 24 hours and that the treatment team should meet as soon as possible but within 24 hours to discuss any potential modification of the treatment plan based on the conditions that led to seclusion, and that a discussion with the individual should take place following seclusion. As noted previously, we have included standards governing the use of seclusion as well as restraints in this rule including the requirement that a physician must order restraint or seclusion. We are allowing a registered nurse to obtain the physician's verbal order at the time that restraint or

seclusion is initiated, but are requiring that the physician's verbal order be followed up with the physician's signature verifying the order. We are requiring that staff be physically present continually assessing and monitoring a resident in restraint or seclusion. We are also requiring that if a resident is a minor as defined in this subpart, the parent or guardian must be notified of the use of restraint or seclusion as soon as possible after the initiation of an emergency safety intervention. While we are not requiring that the treatment team meet within 24 hours of a resident being restrained or secluded, we are requiring that if the physician ordering the use of restraint or seclusion is not the resident's treatment team physician, then the ordering physician or a registered nurse must consult with the resident's treatment team physician as soon as possible. Some of these commenters recommended that seclusion be supervised by a psychiatrist or licensed psychologist. We agree with the need for supervision of a resident in restraint as well as seclusion but do not agree that supervision should be performed by a psychiatrist or licensed psychologist because the services of a psychiatrist or licensed psychologist may not always be available in these facilities. However, to ensure resident safety, we are requiring that clinical staff continually monitor and assess a resident in restraint or seclusion.

One commenter stated that only the least intrusive passive restraints for the protection of the individual or others be used and that we not allow seclusion or time out rooms or chemical restraints, mechanical restraints or adverse conditioning. We are not adopting the recommendation that we restrict a facility's use of restraints to the least intrusive passive restraints. While we recognize the commenter's concern, we believe that the type of intervention used to protect a resident should be the decision of the professionals involved with the situation. Our standards governing orders for restraint and seclusion require a physician to order the least restrictive intervention that is most likely to be effective in the emergency safety situation. Furthermore, we have included standards requiring that staff receive education and training in identifying behavior and events that may trigger an emergency safety situation, as well as education and training in the use of nonphysical intervention skills such as de-escalation, active listening and mediation conflict resolution. With regard to the comment that time out not

be allowed, we have defined "time out" to clarify that it is not a form of seclusion, because the resident in time out cannot be physically prevented from leaving the time-out area.

Four commenters stated we should entirely prohibit the use of restraints on youngsters and that only time out and other means should be used in times of crisis. As stated above, we believe that the type of intervention used to ensure the safety of a resident or others in an emergency safety situation should be the decision of the professionals involved in that specific situation. These commenters also contended that restraints are too often justified on the basis of self-protection when they are really used for staff convenience, and that if restraints are allowed in certain circumstances, it is not possible to monitor for improper use. We recognize the commenter's concern and, therefore, our restraint and seclusion policy states that a resident has the right to be free from restraint or seclusion, of any form, used as a means of coercion, discipline, convenience, or retaliation. We believe that the standards governing restraint and seclusion, including allowing only a board-certified psychiatrist or a licensed physician to order restraint or seclusion, imposing time limits on the use of restraint and seclusion that are consistent with JCAHO standards, requiring continual monitoring and assessment of residents in restraint or seclusion, and requiring that a resident's record be documented each time restraint or seclusion is used, will serve to ensure the safety of residents and diminish the inappropriate use of restraint and seclusion.

One commenter stated that a resident's parents should be notified within 24 hours whenever seclusion is used and that the treatment team should meet as soon as possible to discuss any needed modification to the plan. The commenter suggested that plan modifications should be based on analysis of the conditions leading to seclusion and discussion with the individual following seclusion. We partially agree with these comments and are requiring a facility to notify the parent(s) or legal guardian(s) of a minor resident who is restrained or placed in seclusion as soon as possible after the initiation of each emergency safety intervention. In addition, we are requiring that postintervention debriefings be conducted within 24 hours after the use of restraint or seclusion. The first debriefing will provide the resident and staff involved in the use of a restraint or seclusion the opportunity to discuss the circumstances that resulted in its use, as

well as opportunity for the resident and staff to develop strategies that can be employed to prevent the future use of restraint or seclusion. A second debriefing between appropriate supervisory and administrative staff and staff directly involved in the restraint or seclusion of a resident must be provided to allow for a review and discussion of the situation that required the use of restraint or seclusion, including a discussion of alternative techniques that staff might have employed and procedures staff could implement to prevent future restraint or seclusion. We are requiring that changes identified through these debriefings be documented in the resident's treatment plan.

One commenter suggested we delete the provision that a facility may not administer any psychoactive drugs for purposes of discipline or convenience from our standard on restraints. The commenter stated that facilities do not "use" drugs, and stated that drugs are prescribed by a physician as clinically appropriate in his or her opinion. The commenter asserted that this provision interferes with the practice of medicine. We agree and have not included this language in our standards governing restraints in this interim final rule. However, we are prohibiting the use of any form of restraint or seclusion used as a means of coercion, discipline, convenience, or retaliation.

One commenter stated that we need program standards for the prescription and administration of medication, especially psychoactive medication. We have rejected the suggestion that we set standards governing the use of medications because we believe to do so would amount to our practicing medicine. We have generally declined to set standards that would limit or preclude the professional discretion of physicians. However, we are prohibiting the use of any form of restraint when used for coercion, discipline, or convenience because these uses are medically unnecessary. Another commenter argued that the standard governing drugs is much too loose and suggested six conditions relating to drug therapy that we should include as part of our standard. As stated above, we do not believe that we have authority to set standards of practice regarding the use of medications. Two commenters suggested we establish a separate condition of participation for pharmacy services because medication is a primary component of active treatment, and risk of medication error is substantial. We have rejected this suggestion at this time because we are currently publishing only standards

governing the use of restraint and seclusion in this interim final rule.

IV. Response to Comments on This Interim Final Rule

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this document, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Waiver of Proposed Rulemaking

In accordance with the requirements of the Administrative Procedures Act (APA), we ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule before the final rule is made effective. The notice of proposed rulemaking required by the APA includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subject matter and issues involved. Consistent with that practice, the November 1994 proposed rule proposed limitations on the use of restraint and seclusion by psychiatric residential treatment facilities that provide inpatient psychiatric services to individuals under age 21 that we have clarified and further developed in this interim final rule. In addition, we provided the public with notice of our heightened concern on this issue in our request for comment in the July 1999 interim final rule on hospital restraint and seclusion standards.

We have made some important additions to the 1994 proposed rule based both on comments received in response to the proposed rule and on the information sources referenced in this preamble. To the extent that there are provisions of this interim final rule that are not a logical outgrowth of the 1994 proposed rule, we are waiving the APA rulemaking procedure. The APA rulemaking procedure can be waived if the agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We believe that the danger and risks to children and adolescents from inappropriate restraint and seclusion practices are substantiated by continued reports of deaths and serious injuries that are occurring in residential settings.

To protect the health and safety of residents, we believe we are justified in applying more prescriptive standards in this interim final rule governing the use of restraint and seclusion in psychiatric residential treatment facilities than those proposed in the November 1994 proposed rule or those promulgated in the July 1999 hospital interim final rule.

Significant public attention has been focused on restraint and seclusion practices in psychiatric residential treatment facilities providing services to children and adolescents. In response to concerns about the inappropriate use of restraint and seclusion in these facilities, the Congress passed and the President signed in October 2000, legislation to regulate the use of restraint and seclusion in facilities that receive Medicare and Medicaid funding. That legislation, the Childrens Health Act of 2000, provides additional explicit statutory authority for many of the provisions of this rule.

As we noted, the *Courant* articles of October 1998 reported that 142 individuals had died in restraint-related incidents in the preceding decade. It was reported that many of these deaths were the result of improper use of mechanical restraints and that some could have been prevented by routine monitoring of the individual. One-third of the deaths reported by the *Courant* were due to asphyxia, and one-quarter were due to cardiac-related causes. As noted earlier, a GAO report published in September 1999, identified 24 deaths associated with restraint or seclusion in fiscal year 1998. The GAO indicated that the source of the data on the number of deaths reported was restraint or seclusion-related deaths that were investigated by the Protection and Advocacy agencies in all 50 states and the District of Columbia in fiscal year 1998. The GAO study concluded that the full extent of related injuries and deaths from improper restraint or seclusion practices is unknown because there is no comprehensive reporting system to track injuries and deaths, or a system that tracks the rates of restraint or seclusion use by a facility. The report stated that because reporting is so fragmentary, many more deaths related to restraint or seclusion may have occurred. And finally, even as we prepare to publish this rule, the media continue to investigate and report abusive practices, including deaths and injuries to children that are the result of inappropriate use of restraint and seclusion in psychiatric residential treatment facilities.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule

on an interim basis because delaying the effective date of the rule would be contrary to public interest. We are providing a 60-day period for public comment.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the sections that contain information collection requirements.

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 § 441.152.

The certification requirement of this section is not new. The paperwork burden is contained in the referenced § 441.152, which specifies the certification requirements, has been approved under OMB #0938-0754.

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 National Center for Health Statistics, *Health, United States* published in 1999 (page 278) which indicated that there were 459 psychiatric residential treatment facilities in 1994, the latest year for which data are available. We estimate an annual growth rate in the number of these facilities to be 2 percent. Using this growth rate, we determined that there would be approximately 475 to 500 psychiatric residential treatment facilities nationally as of FFY 2001. These data showed that there are approximately 70 residents per facility at any one time. This equates to a total nationwide bed capacity approximating 35,000 beds. 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 47,500 residents nationally. 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.

Thus, there will be a one-time burden of 4,000 hours nationwide to develop the statement and an annual burden of 48 hours per psychiatric residential treatment facility and 23,750 hours nationally to disclose the policy.

Section 483.358 Orders for the Use of Restraint or Seclusion

In accordance with paragraph (d) of this section, a physician's verbal order must be obtained by a registered nurse at the time the emergency safety intervention is initiated by staff if a written order cannot be easily obtained, and the verbal order must be followed with the physician'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 this section, each order for restraint or seclusion must be documented in the

resident's record. Documentation must include—

- (1) The ordering physician'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, or approximately 282,000 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 141,000 hours annually to comply with the documentation requirements.

In accordance with paragraph (i) of this section, 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 70,500 hours annually to comply with this documentation requirement.

In accordance with paragraph (j) of this section, the physician ordering the restraint or seclusion must sign the order in the resident's record as soon as possible, but no later than 24 hours after the order is issued.

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) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities.

§ 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 and inform the team physician of the emergency safety situation that required the resident to be restrained or

placed in seclusion. Paragraph (f) 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 30 minutes per situation, 282 hours annually per psychiatric residential treatment facility, or 141,000 hours nationally to comply with the documentation and disclosure requirements of this section, 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)

If the resident is a minor as defined in § 483.352, paragraph (a) of this section 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 this section requires the facility to 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 and 15 minutes to document that notification. The total annual burden will be 423 hours per psychiatric residential treatment facility and 211,500 hours nationally, based on the assumption that virtually all of the residents will be minors as defined in § 483.352.

Section 483.370 Postintervention 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 30 minutes per situation, or an annual burden of 282 hours per psychiatric residential treatment facility and 141,000 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—

- (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) because 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 500 multiplied by 8, or 4,000 hours.

Paragraph (b) of this section requires that the facility 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. 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. 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.

Staff must document in the resident's record that the contacts above were made.

The burden for notifying parent(s) or legal guardian(s) is addressed under § 483.366.

We estimate that it will take an additional 15 minutes to document that

these contacts were made, for an average annual burden of 141 hours per psychiatric residential treatment facility, with an annual national total of 70,500 burden hours.

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 § 483.376 was successfully completed.

While these information collection requirements are subject to the PRA, we believe the burden associated with them are 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.

Comments

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Health Care Financing Administration,
Office of Information Services,
Security and Standards Group, Attn:
Julie Brown, Room N2-14-26, 7500
Security Boulevard, Baltimore, MD
21244-1850;

and
Office of Information and Regulatory
Affairs, Office of Management and
Budget, Room 10235, New Executive
Office Building, Washington, DC
20503, Attn: Brenda Aguilar, HCFA
Desk Officer.

VII. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of this interim final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$5 million or less annually. For purposes of the RFA, all psychiatric residential treatment facilities are considered to be small entities. Individuals and States are not included in the definition of a small entity. Consistent with the RFA, we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities.

Also, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. That analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds. This regulation does not have an impact on small rural hospitals. However, to the extent the rule may have significant effects on psychiatric residential treatment facilities and their residents, or be viewed as controversial, we believe it is desirable to inform the public of our projections of the likely effects of the proposals.

The Unfunded Mandates Reform Act of 1995 requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits for any rule that may result in a mandated expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more. This rule has no mandated consequential effect on State, local, or on tribal governments, or the private sector. We have described the anticipated effects of this regulation below.

We have reviewed this interim final rule with comment under the threshold criteria of Executive Order 13132, Federalism. We have determined that this interim final rule with comment does not significantly affect the rights, roles, and responsibilities of States.

This rule is the product of serious concern about improper use of restraints and seclusion in psychiatric residential treatment facilities. This led us to set forth this interim final rule with comment to ensure the protection of residents of these facilities from improper restraint and seclusion

practices that could contribute to death or serious injury.

B. Anticipated Effects

1. Effect on Psychiatric Residential Treatment Facilities

We believe that many psychiatric residential treatment facilities are already in compliance with this rule because of State laws governing the use of restraint and seclusion, as well as their own quality assurance and improvement systems. Additionally, psychiatric residential treatment facilities must meet current Federal requirements for accreditation in order to provide inpatient psychiatric services to individuals under age 21. We are aware that the national accrediting organizations are currently in the process of revising their standards governing the use of restraint and seclusion. Therefore, the impact of this rule will not be determinable to the extent that the accrediting organizations' revised restraint and seclusion standards are or are not compatible with the requirements of this rule.

There are several provisions that will have an impact on psychiatric residential treatment facilities. The facilities will have to notify a parent(s) or a legal guardian(s) when restraint or seclusion is used, and ensure that staff are provided with initial and ongoing education and training in the proper and safe use of seclusion and the proper and safe use of restraint, and in techniques and alternative methods for handling resident behavior, symptoms, and situations that traditionally have been treated by the use of restraints or seclusion.

There will be facility costs associated with developing a policy on the use of restraint and seclusion in emergency safety situations and ensuring that this policy statement is available to residents and family members as well as facility staff.

We anticipate that some facilities will need additional registered nurses to be present during all shifts, including weekends, because we are requiring that, when a physician is not present to order the use of restraint or seclusion, a registered nurse must be present to obtain the physician's verbal order, and to contact the ordering physician should an emergency safety situation continue beyond the time limit of the physician's order. In addition, when a physician is not available, we are requiring a registered nurse to perform the 1 hour assessment of an individual who is restrained or secluded, and to evaluate

the resident's well-being after he or she is removed from restraint or seclusion.

While psychiatric residential treatment facilities generally offer a less restrictive alternative to hospital treatment of psychiatric conditions, they are recognized as an inpatient setting for the purposes of providing mental health services under the Medicaid Inpatient Psychiatric Services Under Age 21 benefit. Unlike hospitals, which have a full cadre of medical professional staff present on a 24-hour basis, psychiatric residential treatment facilities may not be required to provide 24-hour coverage by licensed medical professional staff. In our informal research, we found that some facilities employ medical professional staff on a less than 24-hour basis. One facility contracts with a physician to provide 24-hour "on-call" coverage which does not equate to continual onsite coverage by medical staff. Since these facilities are providing medically necessary services in an inpatient setting, we believe that medical professional staff should be present on a 24-hour basis.

An emergency safety situation involving a resident of a facility can occur at any time, requiring staff to use restraints or seclusion as an emergency intervention to ensure the resident's safety or the safety of others. These emergencies often occur in the evening or on weekends when staffing levels may be lower than during the day. When such a situation occurs in a hospital, trained medical professional staff are onsite 24 hours a day to assist in the proper and safe application and monitoring of restraints. However, while psychiatric residential treatment facilities provide essentially the same inpatient care to vulnerable children and adolescents, trained medical professional staff are not required to be present 24 hours a day. This disparity creates increased risk for serious injury or even death when staff are faced with an emergency safety situation requiring the use of restraint or seclusion. Therefore, we believe that it is not only reasonable but critical to resident safety that we require these facilities to provide 24-hour onsite coverage by a registered nurse. It would be irresponsible not to extend the same level of protections to children and adolescents in these facilities that are provided in a hospital.

In addition, this rule requires psychiatric residential treatment facilities to report both to the State Medicaid agency and the State-designated P&A system, any serious occurrence, including a resident's death, a serious injury to a resident, or a

resident's suicide attempt. 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. We believe that this new reporting requirement will have only a minimal cost impact on facilities.

The *Hartford Courant*, a Connecticut newspaper, heightened public awareness of this issue with a series of articles in October 1998 citing the results of a study that identified 142 deaths from the use of seclusion and restraint in behavioral health treatment facilities over the past 10 years. However, this number includes deaths from the use of seclusion and restraint in more than just the psychiatric residential treatment facility setting. We believe the nationwide reporting of deaths and serious injuries in psychiatric residential treatment facilities will contribute to the reduction of deaths or serious injuries that result from the inappropriate use of restraint and seclusion.

We believe that there will be costs associated with developing and implementing training programs for facility staff. However, we are not prescribing how facilities will meet the training requirements. Therefore, psychiatric residential treatment facilities will be afforded the flexibility to provide the training directly through "in-house" training or to obtain a contractor to provide the training either at the facility or off-site.

2. Effect on Beneficiaries

The implementation of this regulation will serve to protect residents and staff of psychiatric residential treatment facilities. We anticipate that the benefits will include a significant reduction in the inappropriate use of restraint and seclusion which will result in a reduction in the number of deaths and serious injuries to residents and facility staff.

3. Effect on Medicaid Program

We expect the implementation of this regulation will generate some costs to the Medicaid program. There will be additional facility costs as described in the table below.

C. Summary of Estimated Costs

The following are the assumptions and the methodology we used to derive the estimated costs for implementing this rule. We are soliciting public comments regarding any available information that may affect the cost estimates associated with the implementation of this rule.

ANNUAL COST
[\$ Millions]

	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005
Psych. Residential Treatment Facility Costs:					
Medicaid—Federal Share	16	31	31	33	34
Medicaid—State Share	12	24	24	25	26
Other Payers	1	3	3	3	3
Total	29	58	58	61	63
State Medicaid Administrative Costs:					
Federal Share	1	1	1	1	1
State Share	1	1	1	1	1
Total	2	2	2	2	2
Fed. Admin. Costs for Survey and Certification					
Total	(1)	(1)	(1)	(1)	(1)

¹Less than \$0.5 million.

Psychiatric Residential Treatment Facility Costs

Psychiatric residential treatment facility costs are comprised of three categories: (1) additional registered nursing staff, (2) staff training, and (3) facility reporting.

Data from *Health, United States, 1999* (National Center for Health Statistics, p. 278) indicate that there were 459 psychiatric residential treatment facilities in 1994, the latest year for which data are available. Resident care staff in these facilities totaled about 44,000 in that same year. Using a 2 percent growth rate trend developed from the *Health US 1999* data above, we projected the number of facilities and the number of resident care staff for Federal fiscal years (FFY) 2001 through 2005.

1. *New staff costs.* The *Health US 1999* data on staffing for psychiatric residential treatment facilities shows an average of 3.2 full-time-equivalent (FTE) registered nurses per facility. The requirement for 24 hour per day registered nurse coverage would require a minimum of 4.2 FTEs (168 hours per week divided by 40 hours per week per FTE). Each facility would, at a minimum, have to provide for an average of one additional FTE registered nurse. For these estimates we have assumed an increase of 1.5 FTE registered nurses per facility, which translates into a requirement for approximately 790 additional registered nurses to provide the necessary coverage in all psychiatric residential treatment facilities in FFY 2001. We trended the registered nurse staffing requirement forward through 2005 based on our estimation that resident population growth would approximate 2 percent per year. The numbers of

registered nurses needed to provide coverage in years subsequent to FFY 2001 will vary with changes in the numbers of residents. We assumed the total annual compensation (salary and fringe benefits) for each registered nurse to be \$56,000 in FFY 2001, totalling \$44.2 million nationally. The total costs are estimated to increase by 3 percent per year thereafter. Data taken from the *Nursing Department Compensation Report 1999–2000* (Hospital and Healthcare Compensation Service, Oakland New Jersey, page 18) indicate that the annual national average base salary for inpatient hospital psychiatric nursing positions (equivalent in skills and payment level to the nurses working in psychiatric residential treatment facilities) would approximate \$19.99 per hour or \$41,580 annually for 1999, the latest year for which data are available. The Report indicates that the average increase in psychiatric nursing salaries approximates 3 percent per year. Using a 3 percent growth rate we projected the annual salary for psychiatric nurses for Federal fiscal years 2001 through 2005. We added a factor of 27.0 percent to psychiatric nurses salary for fringe benefit costs. The term fringe benefits includes paid leave, supplemental pay, insurance, retirement, savings and other benefits. The 27.0 percent was shown for nurse fringe benefit costs in the publication: *Employer Costs for Employee Compensation, 1986–1998*, Table 2, Employer Costs Per Hour Worked for Employee Compensation and Costs as a Percent of Total Compensation: Civilian Workers, by Occupational and Industry Group, March 1998” (U.S. Department of Labor, Bureau of Labor Statistics, page 10). The rate of fringe benefits to salary ranged from 27.0 to 27.7 percent over the period from March 1994

through March 1998, with the majority at 27.0 percent, as shown in Tables 2, 18, 34, 50, and 66 of the same publication. The year 1998 is the latest period for which such data are available. As a result, we used 27.0 percent as a constant in our cost projection for Federal fiscal years 2001 through 2005 as any variation in rate would represent a very limited change in projected fringe benefit costs.

2. *Training costs.* Existing Federal Medicaid regulations at 42 CFR 441.151 require that a psychiatric facility that provides inpatient psychiatric services to individuals under age 21 be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), 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. Most of these facilities are currently accredited by JCAHO. In August 2000, JCAHO published its Comprehensive Accreditation Manual for Hospitals, which includes revised behavioral health care standards governing the use of restraint and seclusion. These revised restraint and seclusion standards apply to all behavioral health care settings, including residential treatment centers. Specifically, JCAHO strengthened existing standards governing training requirements for direct care staff in the safe use of restraint and seclusion and the requirement for education and assessment of staff competence in minimizing the use of restraint and seclusion. These new standards will take effect January 1, 2001.

We have made the following assumptions with regard to staff training: (1) That the revised JCAHO

training requirements for facility accreditation will not fully meet the training requirements under this interim final rule, and therefore have included estimated costs for staff training which we obtained through research on consultants who provide this specific service; (2) that, at a minimum, staff training to meet the requirements of this rule would cost approximately \$250 per staff person for initial training, and approximately \$100 annually for ongoing staff training, and (3) that only 10 percent of staff would fully meet the training requirements under this rule.

We estimated that by FFY 2001 the facility staff would have grown to approximately 50,000 from the 44,000 staffing estimate for 1994 (see page 69). We assume that approximately 90 percent of the facility staff, or about 45,000 employees would require training in the use of restraint and seclusion. We estimate that approximately 75 percent of the staff to be trained, or 33,750, would require initial training at an estimated \$250 per person, totaling approximately \$8.4 million. The remaining 11,250 staff would require ongoing training at about \$100 per employee, amounting to an estimated \$1.1 million.

In addition to direct training costs, we also assumed that facilities would incur related consulting costs averaging 10 hours per month per facility at a cost of \$40 per hour. Inflation for all training and related costs was assumed to be 5 percent per year.

3. *Reporting costs.* In the absence of any current verifiable data on serious occurrences involving residents in psychiatric residential treatment facilities, we have assumed the costs of the required reporting of these events to be approximately \$250 per facility, per year. We are soliciting comments regarding any available information on actual reporting costs.

Total estimated facility costs of compliance, as shown in the above table, are estimated to be \$58 million in the first full year of implementation (FFY 2002). This figure represents about 1.6 percent of the total projected expenditures of \$3.3 billion for psychiatric residential treatment facilities in that year, as derived from the *Health US 1999* data.

State Medicaid Administration Costs

States will have additional responsibilities and costs for survey and certification requirements associated with the requirements of this regulation. Beginning in Federal fiscal year 2001, we project there will be 500 residential treatment facilities, or an average of 10 facilities per state. For each state, we

estimated an annual survey agency cost equivalent to 5 days to conduct 2 onsite reviews (20 percent sample) to validate facility attestation to our new restraint and seclusion standards. We also estimated that documentary reviews of facility attestations, including any necessary follow up with facilities in conjunction with the attestation would require the survey agency to incur costs equivalent to 5 days. We also estimated costs associated with restraint and seclusion complaints which would require investigation by the survey agency. We estimated 2 complaints annually requiring onsite follow up by the survey agency, including enforcement activities and appeals-related activities. We estimated each complaint would require 2 days for onsite visits, 2 days for follow up and 1 day for appeals-related activities for a total of 10 days for 2 complaints. We assumed the need for an additional one-tenth of an FTE per state to support this additional workload.

Current expenditures indicate an average cost (salary and benefits) of \$50,000 for state survey agency professional personnel; one-tenth of one FTE would cost \$5,000 per year. Because these are Medicaid-only facilities, the survey and certification costs will be paid under the Medicaid program. Based on the current 75/25 Federal-state match, the average expenditures for each state would be \$3,750 in Federal Medicaid funds, and \$1,250 in state-matching funds.

Other Assumptions

Available evidence indicates that residents of psychiatric residential treatment facilities are overwhelmingly Medicaid-eligible. Therefore, we have assumed that 95 percent of the costs incurred by these facilities to implement these new regulations would be defrayed by the Medicaid program and 5 percent by other payers. We are assuming that States will continue to fully fund the costs of this benefit.

D. Alternatives Considered

We originally considered developing one set of requirements regulating the use of restraint and seclusion for all provider types in the Medicare and Medicaid programs. However, based on public comments received in response to the interim final regulation addressing a similar CoP for hospitals, and recent concerns about restraint and seclusion use for behavior management situations, we concluded that one set of requirements did not afford all patients (or residents) with adequate protections. Moreover, with the enactment of the Children's Health Act of 2000, the

Secretary no longer has the discretion to leave this benefit unregulated.

E. Conclusion

The CoP for psychiatric residential treatment facilities sets forth a series of requirements to ensure each resident's physical and emotional health and safety. These requirements address each resident's right to be free from restraint or seclusion, of any form, used as a means of coercion, discipline, convenience, or retaliation. The CoP is a new requirement for facilities that provide inpatient psychiatric residential treatment services to Medicaid eligible individuals under age 21. In accordance with the Regulatory Flexibility Act, we have examined the burden this rule may impose on small entities and certify that this rule will not have a significant impact on a substantial number of entities.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 441

Family planning, Grant programs-health, Infants and children, Medicaid, Penalties, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs-health, Health facilities, Health professionals, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

For the reasons set forth in the preamble, 42 CFR chapter IV is amended as follows:

PART 441—SERVICES: REQUIREMENTS AND LIMITS APPLICABLE TO SPECIFIC SERVICES

A. Part 441 is amended as set forth below:

1. The authority citation for part 441 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. Section 441.151 is revised to read as follows:

§ 441.151 General requirements.

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

(1) Provided under the direction of a physician;

(2) Provided by—

(i) A psychiatric hospital or an inpatient psychiatric program in a hospital, accredited by the Joint Commission on Accreditation of Healthcare Organizations; or

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

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

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

(ii) The date the individual reaches 22; and

(4) Certified in writing to be necessary in the setting in which the services will be provided (or are being provided in emergency circumstances) in accordance with § 441.152.

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

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

B. Part 483 is amended as set forth below:

1. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

2. A new subpart G, consisting of §§ 483.350 through 483.376, is added to part 483 to read as follows:

Subpart G—Condition of Participation for the Use of Restraint or Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services for Individuals Under Age 21

Sec.

483.350 Basis and scope.

483.352 Definitions.

483.354 General requirements for psychiatric residential treatment facilities.

483.356 Protection of residents.

483.358 Orders for the use of restraint or seclusion.

483.360 Consultation with treatment team physician.

483.362 Monitoring of the resident in and immediately after restraint.

483.364 Monitoring of the resident in and immediately after seclusion.

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

483.368 Application of time out.

483.370 Postintervention debriefings.

483.372 Medical treatment for injuries resulting from an emergency safety intervention.

483.374 Facility reporting.

483.376 Education and training.

Subpart G—Condition of Participation for the Use of Restraint or Seclusion in Psychiatric Residential Treatment Facilities Providing Inpatient Psychiatric Services for Individuals Under Age 21

§ 483.350 Basis and scope.

(a) *Statutory basis.* Sections 1905(a)(16) and (h) of the Act provide that inpatient psychiatric services for individuals under age 21 include only inpatient services that are provided in an institution (or distinct part thereof) that is a psychiatric hospital as defined in section 1861(f) of the Act or in another inpatient setting that the Secretary has specified in regulations. Additionally, the Children's Health Act of 2000 (Pub. L. 106–310) imposes procedural reporting and training requirements regarding the use of restraints and involuntary seclusion in facilities, specifically including facilities that provide inpatient psychiatric services for children under the age of 21 as defined by sections 1905(a)(16) and (h) of the Act.

(b) *Scope.* This subpart imposes requirements regarding the use of restraint or seclusion in psychiatric residential treatment facilities, that are not hospitals, providing inpatient psychiatric services to individuals under age 21.

§ 483.352 Definitions.

For purposes of this subpart, the following definitions apply:

Drug used as a restraint means any drug that—

(1) Is administered to manage a resident's behavior in a way that reduces the safety risk to the resident or others;

(2) Has the temporary effect of restricting the resident's freedom of movement; and

(3) Is not a standard treatment for the resident's medical or psychiatric condition.

Emergency safety intervention means the use of restraint or seclusion as an 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 purpose of restricting the free movement of a resident's body.

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.

§ 483.356 Protection of residents.

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

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

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

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

(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.

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

(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).

(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;

(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;

(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

(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).

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

§ 483.358 Orders for the use of restraint or seclusion.

(a) Only a board-certified psychiatrist, or a physician licensed to practice medicine with specialized training and experience in the diagnosis and treatment of mental diseases, may order the use of restraint or seclusion.

(b) If the resident's treatment team physician is available, only he or she can order restraint or seclusion. If the resident's treatment team physician is unavailable, the physician covering for the treatment team physician can order restraint or seclusion. The covering physician must meet the same requirements for training and experience described in paragraph (a) of this section.

(c) The physician 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.

(d) If the physician is not available to order the use of restraint or seclusion, the physician's verbal order must be obtained by a registered nurse at the time the emergency safety intervention is initiated by staff and the physician's verbal order must be followed with the physician's signature verifying the verbal order. The ordering physician must be available to staff for consultation, at least by telephone, throughout the period of the emergency safety intervention.

(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.

(f) Within 1 hour of the initiation of the emergency safety intervention, a physician or clinically qualified registered nurse trained in the use of emergency safety interventions 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.

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

(1) The ordering physician's name;

(2) The date and time the order was obtained; and

(3) The emergency safety intervention ordered, including the length of time for which the physician authorized its use.

(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:

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

(2) The time the emergency safety intervention actually began and ended.

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

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

(5) The name of staff involved in the emergency safety intervention.

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

(j) The physician ordering the restraint or seclusion must sign the order in the resident's record as soon as possible.

§ 483.360 Consultation with treatment team physician.

If the physician ordering the use of restraint or seclusion is not the resident's treatment team physician, the ordering physician or registered nurse 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

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

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

(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.

(b) If the emergency safety situation continues beyond the time limit of the physician's order for the use of restraint, a registered nurse must immediately contact the ordering physician in order to receive further instructions.

(c) A physician, or a registered nurse trained in the use of emergency safety interventions, must evaluate the resident's well-being immediately after the restraint is removed.

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

(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.

(b) A room used for seclusion must—

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

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

(c) If the emergency safety situation continues beyond the time limit of the physician's order for the use of seclusion, a registered nurse must immediately contact the ordering physician in order to receive further instructions.

(d) A physician, or a registered nurse trained in the use of emergency safety interventions, must evaluate the resident's well-being immediately after the resident is removed from seclusion.

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

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

(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.

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

§ 483.368 Application of time out.

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

(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 or other residents (inclusionary).

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

§ 483.370 Postintervention debriefings.

(a) Within 24 hours after the use of 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.

(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 a discussion of the precipitating factors that led up to the intervention;

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

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

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

(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, names of staff that were excused from the debriefing, and any changes to the resident's treatment plan that result from the debriefings.

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

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

(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—

(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;

(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.

(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.

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

§ 483.374 Facility reporting.

(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 HCFA's standards governing the use of restraint and seclusion. This attestation must be signed by the facility director.

(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.

(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 § 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.

(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.

(3) Staff must document in the resident's record that the serious occurrence was reported to both the State Medicaid agency and the State-designated Protection and Advocacy system, including the name of the person to whom the incident was reported. A copy of the report must be maintained in the resident's record, as

well as in the incident and accident report logs kept by the facility.

§ 483.376 Education and training.

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

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

(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

(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.

(b) Certification in the use of cardiopulmonary resuscitation,

including periodic recertification, is required.

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

(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.

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

(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.

(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.

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

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: December 21, 2000.

Robert A. Berenson,

Acting Deputy Administrator, Health Care Financing Administration.

Dated: December 28, 2000.

Donna E. Shalala,

Secretary.

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