

deletion areas of the California Gulch Superfund Site remain eligible for future Fund-financed response actions. Furthermore, this partial deletion does not alter the status of the other OUs of the Site which are not being deleted and remain on the NPL. EPA, with concurrence from the State of Colorado, has determined that all appropriate CERCLA response actions have been completed at OU 2 and protection of human health and the environment has been achieved in this area. Therefore, EPA is deleting the Malta Gulch area of the California Gulch Superfund Site from the NPL. This action will be effective July 23, 2001. However, if EPA receives dissenting comments by June 21, 2001, EPA will publish a document that withdraws this action.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: February 12, 2001.

Jack W. McGraw,

Acting Regional Administrator, Region 8.

Part 300, Title 40 of Chapter 1 of the Code of Federal Regulations is amended as follows:

PART 300—[AMENDED]

1. The authority citation for part 300 continues to read as follows:

Authority: 42 U.S.C. 9601–9657; 33 U.S.C. 1321(c)(2); E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp.; p. 351, E.O. 12580, 52 FR 2923, 3 CFR 1987 Comp., p. 193.
[Amended]

2. Table 1 of appendix B to part 300 is amended by revising the entry for “California Gulch” so that it reads as follows:

TABLE 1.—GENERAL SUPERFUND SECTION

State	Site name	City/County	Notes
*	*	*	*
CO	California Gulch.	Leadville	P
*	*	*	*

P = Sites with partial deletion(s).

[FR Doc. 01–12710 Filed 5–21–01; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 441 and 483

[HCFA–2065–IFC2]

RIN 0938–AJ96

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

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

ACTION: Interim final rule; amendment and clarification with request for comment.

SUMMARY: On January 22, 2001, we published an interim final rule with comment period (66 FR 7148) that established 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. The interim final rule established standards for the use of restraints or seclusion that psychiatric residential treatment facilities must have in place to protect the health and safety of residents.

In response to some of the concerns submitted in comments on that interim rule, this document clarifies what facilities are subject to the requirements of the interim final rule, modifies reporting requirements to facilitate HCFA monitoring, and amends staffing requirements applicable to restraints and seclusion.

Due to the operational significance of these issues, amendment to the interim final rule is required by the May 22, 2001 effective date of the interim final rule. Without such amendments, we are concerned that substantial numbers of facilities would not be able to comply with certain requirements of our interim final rule, and that beneficiaries will suffer needless displacement from those facilities. We are also concerned that HCFA will not be able to timely obtain data necessary to monitor for situations involving jeopardy to program beneficiaries. We will accept comments on these amendments, and will address all comments on the interim final rule and these amendments at a later date.

DATES: *Effective date:* May 22, 2001.

Comment date: Comments concerning these amendments to the interim final rule will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on July 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–IFC2, 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–IFC2.

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

On January 22, 2001, we published an interim final rule with comment period (66 FR 7148) that defined a “psychiatric residential treatment facility” that is not a hospital and that may furnish covered Medicaid inpatient psychiatric services for individuals under age 21. The interim final rule established standards for the use of restraints or seclusion in psychiatric residential treatment facilities to protect the health and safety of residents.

Section 3207 of the Children’s Health Act of 2000 (Pub. L. 106–310) requires that health care facilities receiving support in any form from any program supported in whole or part with funds appropriated to any Federal department or agency shall protect and promote the

rights of each resident of a facility, including the right to be free from any restraint or involuntary seclusion imposed for purposes of discipline or convenience. This Act permits the Secretary to issue regulations that afford residents greater protections regarding restraint and seclusion than the standards published in the new law. Our interim final rule provides greater protections than those required in section 3207.

II. Clarification of Applicability of the Rule

This document clarifies the facilities that are subject to the requirements of the January 22, 2001 interim final rule. It became apparent from the number of comments we received to the interim final rule that many facilities are unclear whether or not they are subject to the requirements of the interim final.

The interim final rule applies to psychiatric residential treatment facilities that receive payment for providing the Medicaid inpatient psychiatric services benefit for individuals under age 21. The Medicaid inpatient psychiatric services benefit for individuals under age 21 may be provided in a psychiatric hospital (that meets the applicable hospital conditions of participation set forth in 42 CFR part 482) or in "another inpatient setting that the Secretary has specified in regulations" pursuant to section 1905(h) of the Social Security Act. As set forth in the interim final rule, psychiatric residential treatment facilities are facilities that are not licensed as hospitals but meet the requirements in 42 CFR part 441 subpart D, the requirements of 42 CFR part 483, subpart G, and have a provider agreement with the state Medicaid agency.

A psychiatric residential treatment facility's payment for inpatient psychiatric services to individuals under age 21 includes compensation for the resident's room and board as well as a comprehensive package of services. This rule does not apply to other providers that receive Medicaid compensation on a service-by-service basis and do not receive Medicaid payment for the individual's room and board. An example would be a facility receiving Medicaid payment for outpatient rehabilitation services.

If a facility is uncertain whether or not this rule applies, it should contact the state Medicaid agency for further information regarding the applicability of this regulation.

Additionally, we have received numerous inquiries regarding the attestation date contained in

§ 483.374(a)(1). This document does not change the requirement that facilities with a current provider agreement must provide its attestation to the State Medicaid agency by July 21, 2001.

III. Amendments to the Interim Final Rule

This document also makes amendments to sections of the rule relating to orders for the use of restraint and seclusion; consultation with the resident's treatment team physician; monitoring of the resident in seclusion or restraint; and facility reporting requirements. The changes being made are in response to the serious and immediate concerns raised by comments submitted on the interim final rule. These comments described the severe shortage of registered nurses as well as the unavailability of psychiatrists as the two major reasons why facilities would not be able to comply with the requirements of our interim final rule. They stated that the shortage of these personnel is a national problem. Although we considered the ordinary costs of additional personnel in additional staffing in issuing the interim final rule, we did not take into account the lack of availability of sufficient numbers of trained individuals to meet those staffing needs. We agree that the scope of the shortage of professionals to provide services in psychiatric residential treatment facilities is critical. As a result, we are concerned that substantial numbers of facilities will be unable to meet the conditions of participation to participate in the Medicaid program and that beneficiaries will be left without adequate placements. Therefore, we have reviewed the requirements in the interim final rule and are amending the rule to permit staffing alternatives that ensure sufficient beneficiary protection but are less burdensome for facilities.

This document also amends our definition of "personal restraint" to clarify that briefly holding without undue force a resident for the purpose of comforting him or her, or holding a resident's hand or arm to safely escort him or her from one area to another is not a restraint. Many commenters stated that our definition is so broad that staff would be prohibited from comforting an upset resident, or holding a resident's hand to safely escort him or her across a street. This was not our intention, and we are concerned that this reading could prevent facilities from participating in the Medicaid program, and result in needless displacement of Medicaid beneficiaries.

This document also amends our requirements for facility reporting of

serious occurrences. We are adding the requirement that a facility must report the death of any resident to the Health Care Financing Administration (HCFA) regional office. This change is required to ensure that HCFA has sufficient timely information to identify threats to beneficiary health and welfare.

The specific changes made in this document are as follows:

Section 483.352 Definitions

In § 483.352, we are amending the definition of "personal restraint" by adding a clarifying statement that "personal restraint" does not include briefly holding without undue force a resident in order to calm or comfort him or her, or holding a resident's hand to safely escort him or her from one area to another.

Section 483.358 Orders for the Use of Restraint or Seclusion

We are amending § 483.358(a) to state that orders for restraint or seclusion must be by a physician, or other licensed practitioner permitted by the state and the facility to order restraint or seclusion and trained in the use of emergency safety interventions. We have included "other licensed practitioner permitted by the state and the facility to order restraint or seclusion" to be consistent with the language in the Children's Health Act of 2000. As with all staff, other licensed practitioners permitted by the state and the facility to order restraint or seclusion and trained in the use of restraints and seclusion as set out in § 483.376. Section 441.151 also requires that inpatient psychiatric services for recipients under age 21 be furnished under the direction of a physician.

We are amending § 483.358(b) to state that if the resident's treatment team physician is available, only he or she can order restraint or seclusion.

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

We are amending § 483.358(d) to state that if the order for restraint or seclusion is verbal, the verbal order must be received by a registered nurse or other licensed staff, such as a licensed practical nurse. The physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion must verify the verbal order in a signed written form in the resident's record. The physician or other licensed

practitioner permitted by the state and the facility to order restraint or seclusion must be available to staff for consultation, at least by telephone, throughout the period of the emergency safety intervention.

We are amending § 483.358(f) to state that a physician or "other licensed practitioner trained in the use of emergency safety interventions, and permitted by the state and the facility to assess the physical and psychological well being of residents" must conduct a face-to-face assessment of the physical and psychological well being of the resident within 1 hour of the initiation of the emergency safety intervention.

We are amending paragraphs (g)(1) and (g)(3) and (j) to include "other licensed practitioner permitted by the state and the facility to order restraint or seclusion".

Section 483.360 Consultation With Treatment Team Physician

We are amending § 483.360 to state that if a physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion orders the use of restraint or seclusion, the resident's treatment team physician must be contacted, unless the ordering physician is in fact the resident's treatment team physician.

Section 483.362 Monitoring of the Resident In and Immediately After Restraint

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

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

Section 483.364 Monitoring of the Resident in and Immediately After Seclusion

We are amending § 483.364(c) to state that if the emergency safety situation continues beyond the time limit of the order for the use of seclusion, a registered nurse or other licensed staff, such as a licensed practical nurse, must immediately contact the ordering

physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion to receive further instructions.

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

Section 483.374 Facility Reporting

We are amending § 483.374 by adding a new paragraph (c) to require that facilities report the death of any resident to the Health Care Financing Administration (HCFA) regional office.

IV. Response to Comments on This Interim Final Rule

We will be accepting comments concerning the amendments to the interim final rule contained in this document.

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 and Waiver of the 30-Day Delay in the Effective Date

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.

In November 1994, we issued a proposed rule that contained limitations on the use of restraints and seclusion by psychiatric residential treatment facilities. The interim final rule clarified and further developed these proposed limitations. To the extent that the interim final rule could not be viewed as a logical outgrowth of the 1994 proposed rule, we found good cause to waive requirements for proposed rulemaking. The APA permits waiver of these requirements if the agency finds

good cause that 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 found good cause based on the strong public interest in preventing deaths and injuries to children that are the result of inappropriate use of restraint and seclusion in psychiatric residential treatment facilities. The full rationale for this finding was set forth in the preamble to the January 22, 2001 interim final rule.

Because we believe that the amendments and clarifications set forth in this document are essential to the effective implementation of the basic requirements of the January 22, 2001 interim final rule, the same concerns expressed in our waiver of proposed rulemaking for that rule apply here. In addition, without the amendments and clarifications set forth in this document, we believe there is a risk that beneficiaries will be needlessly displaced as substantial numbers of facilities terminate participation in the Medicaid program as psychiatric residential treatment facilities. In particular, absent clarification of the term "personal restraint," facilities could be terminated for failure to meet conditions of participation for actions that do not warrant concern. Absent changes to staffing requirements, nationwide nurse and psychiatrist shortages could mean that numerous facilities would become unable to meet the conditions of participation. The amendments contained in this document will provide adequate beneficiary protections in a less burdensome manner and will minimize potential beneficiary displacement. In addition, the changes in this document to include HCFA in reporting requirements are necessary to ensure that HCFA has timely information to monitor jeopardy to program beneficiaries.

In sum, we find good cause to waive asking for comment on these amendments to the January rule before making them effective, based on the public interest of avoiding displacement and other potential harm to program beneficiaries. We invite parties to submit comments on these changes, which we will consider in crafting the final rule that applies to these psychiatric residential treatment facilities.

In addition, we find good cause to waive requirements for a 30 day delay in the effective date of these clarifications and amendments to the interim final rule. Under the APA, publication of a substantive rule must

be not less than 30 days before its effective date, unless otherwise provided by the agency for good cause found and published with the rule. These clarifications and amendments are an integral operational part of the overall interim final rule. A delay in the effective date for these clarifications and amendments would be contrary to public interest because a delay would result in inconsistent standards for affected facilities over a relatively short time period. Moreover, there would be some possibility of disruption of services to program beneficiaries to the extent that facilities elect not to continue participation in the Medicaid program until the amendments and clarifications become effective. Moreover, a delay in the effective date would be impracticable to administer because facility guidance, quality monitoring and surveyor training are not designed to accommodate rapid changes in applicable standards. In sum, we find that a 30 day delay in the effective date would be both impracticable and contrary to the public interest because the delay would not be administratively feasible and would risk inconsistent facility standards and potential disruption of services to beneficiaries.

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.

The information collection requirements in the interim rule published in the **Federal Register** on January 22, 2001, as well as the amendments made in this regulation have been approved by OMB through November 30, 2001 under OMB control number 0938-0833. We solicited

comments on these requirements in the January 22, 2001 interim final rule, and have made minimal changes to the requirements in this rule. We are again soliciting public comment on each of these issues for the sections that contain information collection requirements. Comments will be considered in evaluating these information collection requirements under the Paperwork Reduction Act.

The following is a summary of the information collection requirements contained in both the January 22 interim rule and in this amendment to the interim rule.

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 or other licensed practitioner's verbal order must be obtained by a registered nurse or other licensed staff, such as a licensed practical nurse, while the emergency safety intervention is being initiated by staff, or immediately after the emergency safety situation ends. The verbal order must be followed with the physician's or other licensed practitioner's signature verifying the verbal order.

This document changes the January 22 interim rule to allow a registered nurse or other licensed staff such as a licensed practical nurse to obtain a verbal order from a physician or "other licensed practitioner permitted by the state and the facility to order restraint or seclusion", and requires the physician or the other licensed practitioner permitted by the state and the facility to order restraint or seclusion that gave the verbal order to verify, by signature, that he or she gave the 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 (g) of this section, each order for restraint or seclusion must be documented in the resident's record. Documentation must include—

- (1) The name of the physician or other licensed practitioner permitted by the

state and the facility to order restraint or seclusion;

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

(3) The emergency safety intervention ordered, including the length of time for which the physician or other licensed physician permitted by the state and the facility to authorize 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 or other licensed practitioner permitted by the state and the facility to order 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.

The revision to this paragraph requires an "other licensed practitioner permitted by the state and the facility to order restraint or seclusion" to sign orders he or she has given. This does not increase the facility's burden, since only one person is still signing.

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

This section requires that, if a physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion orders the use of restraint or seclusion and he or she is not the resident's treatment team physician, then the ordering physician or other licensed practitioner permitted by the state and the facility to order restraint or seclusion 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 and document the time the team physician was consulted.

Paragraph (b) of this section requires the facility to document in the resident's record the date and time the team physician was consulted.

The amendments to the January 22 interim rule, made by this document, require an "other licensed practitioner permitted by the state and the facility to order restraint or seclusion" to follow the same procedures as a physician. This change does not change the burden from that stated in the original interim rule. In that rule, we stated that 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.

In this document, we have added an amendment to § 483.374 by adding a new paragraph (c) to require that the facility report the death of any resident to the HCFA regional office. 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.

We estimate that these notifications will take a total of 15 minutes. This will total an estimated 141 hours per year per facility and 70,500 nationally, for the estimated 282,000 incidents per year.

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.

The total information collection requirements associated with this regulation will total an estimated 877,750 hours.

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) (Pub. L. 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

Effect on Psychiatric Residential Treatment Facilities

We still maintain that some facilities will need additional staff as a result of the previous interim final rule. The January 22 interim final rule estimated this burden based on the requirement for only registered nurses. This rule does not eliminate that requirement but permits facilities to fulfill this

requirement by allowing other licensed practitioners in lieu of registered nurses.

As stated in our impact statement of January 22, 2001, 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 or other licensed practitioner permitted by the State and the facility. We believe it is appropriate to extend the same level of protections to children and adolescents in these facilities that are provided to them in a hospital.

We are adding a requirement for facilities to report the death of any resident to the HCFA regional office. We are soliciting comments only on this additional HCFA reporting requirement. We believe this additional reporting requirement will have a minimal financial impact on facilities.

C. Summary of Estimated Costs

Psychiatric Residential Treatment Costs

Because of our modification of the rule concerning the use of registered nurses, we have revised this section of the impact statement concerning new staff costs. We recognize that some facilities will need to hire either additional registered nurses or other licensed practitioners permitted by the State and the facility to meet the requirement for 24-hour per day coverage in these facilities. As a result of our modification of the rule, each facility would have to provide for one additional FTE registered nurse or other licensed practitioner permitted by the state and the facility. We did not change the overall estimated numbers of additional FTEs to provide the necessary coverage in all facilities. Our earlier impact analysis can be found in the January 22, 2001 interim final rule.

D. Alternatives Considered

The changes made in this document are being made after further consideration of alternatives discussed in the January 22, 2001 interim final rule.

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, as amended at 66 FR 7148 (January 22, 2001) and 66 FR 15800 (March 21, 2001) is further amended as follows:

PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

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. In § 483.352, the definition of “Personal restraint” is revised to read as follows:

§ 483.352 Definitions.

* * * * *

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

* * * * *

3. Section 483.358 is amended by:

A. Revising paragraphs (a), (c), and (d), (f) introductory text, (g)(1), (g)(3) and (j)

B. Amending paragraph (b) by removing the last two sentences.

§ 483.358 Orders for the use of restraint or seclusion.

(a) Orders for restraint or seclusion must be by a physician, or other licensed practitioner permitted by the

State and the facility to order restraint or seclusion and trained in the use of emergency safety interventions. Federal regulations at 42 CFR 441.151 require that inpatient psychiatric services for recipients under age 21 be provided under the direction of a physician.

* * * * *

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

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

* * * * *

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

* * * * *

(g) * * *

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

* * * * *

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

* * * * *

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

* * * * *

4. Section 483.360 is amended by revising the introductory text to read as follows:

§ 483.360 Consultation with treatment team physician.

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

* * * * *

5. Section 483.362 is amended by revising paragraphs (b) and (c) to read as follows:

§ 483.362 Monitoring of the resident in and immediately after restraint

* * * * *

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

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

6. Amending section 483.364 by revising paragraphs (c) and (d) to read as follows:

§ 483.364 Monitoring of the resident in and immediately after seclusion

* * * * *

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

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

7. Section 483.374 is amended by adding paragraph (c) to read as follows:

§ 483.374 Facility reporting.

* * * * *

(c) *Reporting of deaths.* In addition to the reporting requirements contained in paragraph (b) of this section, facilities must report the death of any resident to the Health Care Financing Administration (HCFA) regional office.

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

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

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

Dated: May 17, 2001.

Michael McMullan,

Acting Deputy Administrator, Health Care Financing Administration.

Dated: May 17, 2001.

Tommy G. Thompson,

Secretary.

[FR Doc. 01-13041 Filed 5-21-01; 8:45 am]

BILLING CODE 4120-01-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CC Docket Nos. 00-257 and 94-129; FCC 01-153]

2000 Biennial Review—Review of Policies and Rules Concerning Unauthorized Changes of Consumers Long Distance Carriers

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The streamlined procedures the Commission adopts here will replace the current, burdensome waiver process. The Commission's new procedures provide for an acquiring carrier to simply self-certify to the Commission, in advance of the transfer, that the carrier will follow the required procedures. This will protect the interests of the affected subscribers by giving them adequate advance notice of the carrier change and ensuring that the change will not cause them financial harm.

DATES: This document contains information collection requirements that have not been approved by the Office of Management Budget (OMB). The Commission will publish a document in the **Federal Register** announcing the effective date of this final rule.

FOR FURTHER INFORMATION CONTACT: Michele Walters, Associate Division

Chief, or Dana Walton-Bradford, Attorney, Common Carrier Bureau, Accounting Policy Division, (202) 418-7400.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's First Report and Order in CC Docket No. 00-257 and Fourth Report and Order in CC Docket No. 94-129 released on May 15, 2001. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY-A257, 445 Twelfth Street, SW., Washington, DC, 20554.

I. Introduction

1. As part of our biennial regulatory review effort, we are amending our carrier change rules to provide a streamlined process for compliance with section 258 of the Communications Act of 1934 (Act), as amended by the Telecommunications Act of 1996 (1996 Act) in situations involving the carrier-to-carrier sale or transfer of subscriber bases. The streamlined procedures we adopt in this Order will replace the current, more burdensome waiver process. Our new procedures provide for an acquiring carrier to simply self-certify to the Commission, in advance of the transfer, that the carrier will follow the required procedures. This will protect the interests of the affected subscribers, consistent with section 258 and our rules, by giving them adequate advance notice of the carrier change and ensuring that the change will not cause them financial harm.

2. The Commission adopted carrier change authorization and verification requirements to protect consumers from fraudulent changes in presubscribed carriers. It has become clear, however, that the need to obtain a waiver of these requirements imposes undue burdens on carriers seeking to buy, sell, or transfer customer accounts and on the Commission that could be avoided without sacrificing consumer protection. These burdens include the time and resources required to prepare and process the waiver petition and any supplemental filings, the regulatory uncertainty inherent in any waiver process, and, oftentimes, delay. Given the dynamic marketplace, and the likelihood that carriers will continue to buy, sell, and transfer customer lines in the future, we believe it is appropriate to streamline our carrier change rules to ensure that they do not inadvertently inhibit routine business transactions, while ensuring that consumers are protected from fraudulent carrier changes, consistent with section 258 and our rules.