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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 482

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Medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights

AGENCY: Centers for Medicare & Medicaid Services (CMS), DHHS.

ACTION: Final rule.

SUMMARY: This final rule finalizes the Patients' Rights Condition of Participation (CoP) which is applicable to all Medicare- and Medicaid-participating hospitals and contains standards that ensure minimum protections of each patient's physical and emotional health and safety. It responds to comments on the following standards presented in the July 2, 1999 interim final rule: Notice of rights; exercise of rights; privacy and safety; confidentiality of patient records; restraint for acute medical and surgical care; and seclusion and restraints for behavior management. As a result of comments received, we have revised the standards regarding restraint and seclusion and set forth standards regarding staff training and death reporting.

DATES: *Effective Date:* These regulations are effective on January 8, 2007.

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I. Background

A. Overview

This rule set forth final requirements for Patients' Rights in hospitals, provides strong patient protections, provides flexibility to providers, and is responsive to comments. This regulation focuses on patient safety and the protection of patients from abuse. These standards support and protect patients' rights in the hospital setting; specifically, the right to be free from the inappropriate use of restraint and seclusion with requirements that protect the patient when use of either intervention is necessary. It recognizes the legitimate use of restraint for acute medical and surgical care as a measure to prevent patient injury, as well as the use of restraint or seclusion to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. In addition, this rule finalizes, without modification, the standards for Notice of Rights, Exercise of Rights, Privacy and Safety, and Confidentiality of Patient Records.

B. Key Statutory Provisions

Sections 1861(e) (1) through (8) of the Social Security Act (the Act) define the term ''hospital'' and list the requirements that a hospital must meet to be eligible for Medicare participation. Section 1861(e)(9) of the Act specifies that a hospital must also meet such other requirements as the Secretary finds necessary in the interest of the health and safety of the hospital's patients. Under this authority, the Secretary has established in regulations at 42 CFR part 482 the requirements that a hospital must meet to participate in the Medicare program.

Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. Regulations at § 440.10(a)(3)(iii) require hospitals to meet the Medicare CoPs to qualify for participation in Medicaid.

The Children's Health Act of 2000 (CHA) (Pub. L. 106–310) was enacted October 17, 2000. Section 3207 of the CHA amended Title V of the Public Health Service Act (PHSA) by adding a new part H, which contains requirements relating to the rights of residents of certain facilities. Specifically, section 591 of the PHS Act, as added by the CHA (42 U.S.C. 290ii), establishes certain minimum requirements with regard to the use of restraint and seclusion in facilities that receive support in any form from any program supported in whole or in part

with funds appropriated to any Federal department or agency. In addition, Sections 592 and 593 of the PHS Act (42 U.S.C. 290ii and 290ii–3) establish minimum mandatory death reporting and staff training requirements. This final rule conforms to the requirements of the CHA.

As implementing regulations are issued, a critical point for consideration is that Title V, part H of the PHS Act is not an isolated enactment, but part of a trend of legislation and regulations aimed at protecting and promoting resident, patient, and client rights. Part H, section 591(c) of the PHS Act states ''This part shall not be construed to affect or impede any Federal or State law or regulations that provide greater protections than this part regarding seclusion and restraint.'' The value of preserving existing law and regulations is recognized while extending protections to those facilities that are currently without the protection intended by the Congress.

C. Regulatory Background

In the December 19, 1997 **Federal Register** (62 FR 66726), we published a proposed rule entitled ''Medicare and Medicaid Programs; Hospital Conditions of Participation; Provider Agreements and Supplier Approval'' to revise the entire set of CoPs for hospitals found at 42 CFR part 482. This proposed rule included a CoP for patients' rights. In the July 2, 1999 **Federal Register** (64 FR 36070), we published the Patients' Rights CoP as an interim final rule with comment. This CoP was separated from the other proposed hospital CoPs in response to Congressional and public interest. Although we have modified some of the provisions to address public comments, these modifications do not lessen protections afforded patients who are restricted or secluded. We note that we have revised the regulation to expand training requirements and have added a requirement that the attending physician or other licensed independent practitioner (LIP) responsible for the care of the patient be consulted as soon as possible when the ''one hour'' evaluation of a patient in restraint or seclusion is conducted by a trained registered nurse (RN) or physician assistant (PA).

D. Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances. In a notice published December 30, 2004 (69 FR 78442), we implemented section 902 of the Act by announcing that all outstanding interim final rules as of December 8, 2003 would be finalized by December 8, 2006 or expire.

This final rule finalizes provisions set forth in the July 2, 1999 interim final rule with comment. In accordance with section 902 and our notice of 2004, this final rule is being published within 3 years of the date of enactment of the MMA, which was December 8, 2003, in order to finalize the 1999 interim final rule with comment.

E. Restraint and Seclusion in Other Settings

In the preamble of the July 2, 1999 interim final rule with comment period, we explained that we were considering the advisability of adopting a consistent restraint and seclusion standard that would apply not only to hospitals but to other kinds of health care entities with which CMS has provider agreements, including those that provide inpatient psychiatric services for individuals under 21 years of age (a program under Medicaid). We asked the public whether we should adopt the same standards that appeared in the July 2, 1999 interim final rule with comment period, or whether we should adopt more stringent standards.

Consumer advocacy groups that commented on extending these requirements to other settings generally argued for more stringent expectations for the care of children, citing special hazards and concerns that arise when children and adolescents are restrained. Some commenters encouraged CMS to apply the restraints and seclusion standards of the interim final rule with comment period to all other Medicaid-funded facilities, particularly residential treatment centers for children and adolescents.

Other commenters did not agree with this approach, arguing that the fields of mental health and developmental disabilities are very different and that similarities between the two should not be assumed. For example, some commenters stated that little research exists on the use of restraint/seclusion in mental health, but that in contrast, a considerable amount of research in the developmental disabilities field supports the effectiveness of restraint and seclusion for severe behavior problems. Thus, the field of developmental disabilities already has extensive guidelines, standards, and rules governing the use of restraint and seclusion.

Some of those commenters who supported uniform restraint and seclusion standards across settings offered detailed suggestions for what those standards should require. For example, commenters suggested that the regulation forbid the use of mechanical restraints for children under a certain age (these commenters offered varying suggestions regarding the threshold age (17 and 21 years of age were two of these suggestions)), or permit therapeutic holding for periods no longer than 15 minutes. Some of the commenters expressed concern about proposing requirements that paralleled existing requirements for hospitals because of the differences in patient acuity and characteristics and treatment.

We considered the comments we received in developing specific restraint and seclusion requirements for inpatient psychiatric services for individuals under 21 years of age. These requirements were published in an interim final rule with comment period entitled, ''Medicaid Program; Use of Restraint and Seclusion in Psychiatric Residential Treatment Facilities Providing Services to Individuals under Age 21'' in the January 22, 2001 **Federal Register** (66 FR 7148). In the May 22, 2001 **Federal Register** (66 FR 28110), we published an additional interim final rule with comment period to amend and further clarify the January 22, 2001 interim final rule with comment period.

There was little comment on extending restraint and seclusion requirements to specific non-behavioral or non-psychiatric types of settings or providers, such as home health agencies, ambulatory surgical centers, or providers of x-ray services. While a few commenters gave blanket support to this idea, they did not supply a rationale for applying one set of standards versus another. Several commenters discussed their concern about extending the restraint and seclusion requirements to the nursing home setting and strongly disagreed with any adoption of the standards presented in the interim final rule with comment period in that setting. One nursing home industry association argued for consistency in terminology and philosophy, but recognized that the settings where beneficiaries receive services are diverse, as are the beneficiaries

themselves, and that adopting a blanket approach might not be practical or appropriate.

After considering these comments and engaging in internal deliberations, we have decided that it would not be appropriate to adopt a detailed, technical approach that would create an identical standard for all of the providers with which CMS has agreements. Instead, the needs of specific treatment populations and settings should drive the types of standards developed. Therefore, we do not plan to adopt the hospital requirements verbatim for other provider types.

However, we are concerned about beneficiaries receiving care in settings where no regulatory protections regarding the use of restraint or seclusion currently exist. The CHA provides statutory protection to patients at any facility receiving Federal funding. While it is impractical, in our view, to take the requirements for hospitals, nursing homes, or intermediate care facilities for the mentally retarded and adopt them as a whole in any other given setting, we can instead develop any new requirements with the same philosophical foundation that underlies the three existing sets of standards and requirements. This foundation encompasses the belief that the patient has the right to be free from unnecessary restraint or seclusion, that using a restraint for convenience, punishment, retaliation, or coercion is never acceptable, and that each patient should be treated with respect and dignity. These beliefs are true in every care setting and are legally enforceable in accordance with the CHA. As appropriate, we will develop regulations that support these concepts. However, given the variations in treatment populations and settings, the individual case setting will drive the type of standards developed which will vary as appropriate.

II. Provisions of the Proposed and Interim Final Rules Regarding Patients' Rights

The December 19, 1997 hospital CoP proposed rule included a patients' rights CoP that proposed to establish standards for the following:

- Notice of rights.
- Exercise of rights regarding care.
- Privacy and safety.
- Confidentiality of patient records.
- Seclusion and restraint.

With the exception of the standard for seclusion and restraint, we received few comments in response to these proposed requirements.

In the July 2, 1999 **Federal Register**, we published an interim final rule with comment period that separated the patients' rights CoP from the other hospital CoPs and introduced modifications to proposed standard (e) and added a new standard (f), governing the use of restraint and seclusion. Because we received few comments on the other provisions of the patients' rights section (standards a through d), these four provisions were not reopened for public comment in the July 2, 1999 interim final rule with comment period.

In the 1997 proposed rule, standard (e) was entitled ''Seclusion and restraint,'' and covered the patient's right to be free of restraint or seclusion used as a means of coercion, convenience, or retaliation by staff. The proposed language set forth several basic ideas and expectations; namely, that restraint (including psychopharmacological drugs used as restraints) and seclusion must be used in accordance with the patient's plan of care; that restraints or seclusion may be used only as a last resort and in the least restrictive manner possible to protect the patient or others from harm; and that restraint or seclusion must be removed or ended at the earliest possible time.

The interim final rule with comment period introduced two standards on restraint and seclusion—one governing the use of restraint in the provision of acute medical and surgical care and the other governing the use of seclusion and restraint for behavior management. The revised standard (e) included definitions that had not specifically appeared in the proposed rule and also included: (1) A prohibition on standing orders or orders on an as needed basis (that is, PRN) for restraint; (2) an emphasis on continual assessment and monitoring; and re-evaluation of the condition of the restrained patient; (3) a requirement that the hospital notify the patient's treating physician if he/she did not issue the restraint order personally; and (4) a training requirement for all staff with direct patient contact. Standard (f) offered definitions and provided more prescriptive requirements than the proposed or revised standard (e). The focus on behavior management in standard (f) was intended to apply in situations where the patient's aggressive or violent behavior creates an emergency situation that places his or her safety or that of others at risk. The more prescriptive elements, such as—(1) requiring a physician or licensed independent practitioner (LIP) to see and evaluate the need for restraint or seclusion within 1-hour of the initiation of the intervention; (2) the limitation on the length of orders and required re-evaluation; and (3) the requirement for continual face-to-face monitoring or continual monitoring using both video and audio equipment if restraint and seclusion are used simultaneously, were meant to be commensurate with the increased risk to patient health and safety when these interventions are used to address violent or aggressive patient behavior.

In both standards (e) and (f) of the July 2, 1999 interim final rule with comment period, the phrase ''psychopharmacological drugs used as restraints'' was replaced with the phrase ''drug used as a restraint,'' in recognition of the idea that singling out one type of medication encourages the misperception that only one class of drugs is used to restrain patients.

Concern for patient health and safety prompted us to make these requirements effective on August 2, 1999. However, given the changes to the proposed standard (e) and the addition of standard (f), we believed that the public should have an opportunity to comment on the revised restraint and seclusion provisions. For these reasons, we published the July 2, 1999 rule as an interim final rule with comment period.

III. Comments on and Responses to the Provisions of the Interim Final With Comment Period

We received approximately 4,200 timely comments on the interim final rule with comment period. Comments were received from hospitals, mental health treatment facilities, physicians, nurses, attorneys, professional associations, accrediting bodies, state agencies, national and State patient protection and advocacy groups, and members of the general public. Many commenters applauded the addition of the restraint and seclusion provisions in the Patients' Rights CoP, even if they disagreed with specific requirements or concepts. A summary of the comments received on these provisions (standards (e) and (f)) and our responses follows.

We received comments on issues out of the scope of the interim final rule with comment period; these comments will not be addressed in this final rule.

A. General Comments on the Requirements for the Use of Restraint and Seclusion

Some commenters suggested that the 1-hour physician or LIP visit and assessment were not consistent with the goal of creating a government that works better and costs less. A few commenters stated that the rapid introduction of standards (e) and (f) was a ''knee-jerk

reaction'' to the lobbying of certain groups and the sensationalized media coverage of a limited number of cases. One commenter stated, ''It is time the legislature and administrative agencies stop reacting to sensational headlines and layering the health care system with costly and time consuming regulations to meet.'' Another commenter questioned the validity of the 1998 Hartford Courant series of articles (cited in the preamble to the interim final rule with comment period), asserting that the articles did not clearly determine that the use of restraint and seclusion were the proximate and sole cause of deaths in the cases cited. The same commenter asked in which setting these deaths occurred, stating that it makes no sense to regulate a hospital on this point if there is no evidence that restraint-related deaths are problematic in hospitals. Another commenter questioned the FDA's estimate of at least 100 deaths per year from improper use of restraints, specifically noting that he believes that these are not cases where restraint use was unmerited. Another commenter stated that while the abuse and deaths that have occurred are unfortunate, they do not represent an emergency situation meriting the actions that were taken by CMS. The commenter made the following statement:

> While 142 deaths in 10 years is unfortunate, the number pales when compared to the 3 million people hospitalized per year for adverse drug reactions and 150,000 deaths resulting from drugs taken properly as prescribed by the physician.

A commenter stated that CMS has given too much credence to over-dramatized accounts of restraint and seclusion use. Many hospitals reported having no injuries or deaths associated with restraint or seclusion use. A number of physicians also noted that none of their patients have suffered serious injuries or died due to the use of restraints. One commenter stated that it was unfair to subject the industry as a whole to highly prescriptive requirements when the events that triggered such concern occurred in a handful of facilities. The commenter argued that only the hospitals where the deaths occurred should be governed by these rules. Another commenter suggested that in the situations where these deaths occurred, the practices used were out of compliance with the hospitals' own policies and procedures. Accordingly, the commenter stated that prescriptive regulations do not represent the gateway to reduced injuries and deaths, and that enforcement of existing requirements would be more effective. Still other commenters have suggested that even if death and injury are of concern, CMS has not yet hit upon the correct solution.

To balance these comments, we mention those received from advocacy groups, patients, and hospital staff. Some of the anecdotal information provided was clearly disturbing, including accounts of patients being choked during takedowns even though staff had been trained in proper procedures, and patients suffering broken limbs or other injuries. Other commenters described situations where patients had been placed in restraints for extended periods of time (up to 10 consecutive hours) and staff did not take vital signs regularly, did not offer food, fluids, or use of the toilet at all, or offered them only once while the patient was restrained. Comments also related concerns about the over use and inappropriate use of restraint or seclusion. One commenter stated that a lawsuit was filed on behalf of a patient dually diagnosed with mental retardation and organic brain syndrome who was placed in restraints 48 times within a six month period. The commenter stated that in the six months after the lawsuit was settled, the patient had only been restrained twice.

Many commenters applauded the regulatory action. Commenters stated that the action was long overdue and important for the safety of vulnerable populations most in need of protection from abuse of restraints and seclusion. Commenters see this rule as a major step forward in addressing issues surrounding the use of restraint and seclusion in inpatient facilities and support further movement toward the goals of ultimately eliminating the use of seclusion and restraint, and preserving patients' rights and dignity. In addition, many commenters stated that they would like to see even more stringent requirements for the use of restraint and seclusion for behavior management.

1. Is There Cause for Concern?

Given the prevalence of restraint use, we believe that awareness and vigilance are justified. On October 11, 1998, the Hartford Courant reported that of the 142 deaths it confirmed, 59.6 percent occurred in the hospital setting (including psychiatric hospitals and psychiatric wards of general hospitals). The Courant further stated that 47.2 percent of the 142 deaths involved physical restraints or therapeutic holds, while 44.1 percent involved mechanical restraint, 3.1 percent involved a combination of the two, and the remaining 5.5 percent were seclusion-related. Although the Courant did not claim that restraint and seclusion use were the sole and proxmate cause of death in each case, we question the usefulness of this criterion in determining whether restraint and seclusion pose significant risk to health and safety. Obviously, when a patient's trachea is crushed during a takedown, restraint would constitute the ''sole and proximal'' cause of death. However, a case cited by one commenter illustrates how this characterization may fail to take into account the many times that restraint or seclusion can play a part in injury. The commenter reported that one young man died after suffering a severe asthma attack soon after fighting with another patient and being restrained. The death was ruled to be due to natural causes, even though the medical examiner found that both the stress of the fight and the restraint triggered the asthma attack. One cannot only consider whether restraint or seclusion is the sole cause of death when examining whether the use of restraint or seclusion poses a significant risk to the patient.

One commenter questioned the statistical significance of 142 deaths over a 10-year period. This number may not reflect the actual number of such deaths that occur each year. In explaining how it conducted its investigation, the Courant noted, ''Throughout the reporting * * * it became clear that many deaths go unreported.'' To better determine the national annual death rate, the Courant hired statistician Roberta Glass, a research specialist for the Harvard Center of Risk Analysis at the Harvard School of Public Health. The Courant reported the following:

> Glass projected that the annual number of deaths could range as high as 150. ''Admittedly, the estimates are only rough approximations,'' Glass said. ''The data needed for precise estimation are not collected in a systematic way nationwide.''

On October 26, 1999, Associate Director Leslie Aronovitz of the U.S. Government Accountability Office provided testimony before the Senate Committee on Finance entitled, ''Extent of Risk from Improper Restraint or Seclusion is Unknown.'' Aronovitz testified to the following:

> Neither the federal government nor the states comprehensively track the use of restraint or seclusion or injuries related to them across all types of facilities that serve individuals with mental illness or mental retardation * * * Because reporting is so piecemeal, the exact number of deaths in which restraint or seclusion was a factor is not known. We contacted the P&As

[protection and advocacy agencies] for each state and the District of Columbia and asked them to identify people in treatment settings who died in fiscal year 1998 and for whom restraint or seclusion was a factor in their death. The P&As identified 24, but this number is likely to be an understatement, because many states do not require all or some of their facilities to report such incidents to P&As.

The lack of systemic information collection is an important point. The Joint Commission on Accreditation for Healthcare Organizations (JCAHO), which accredits 80 percent of the hospitals that participate in Medicare and Medicaid, does not require hospitals to report ''sentinel events'' such as injuries or deaths related to restraint or seclusion use, but encourages voluntary reporting through its sentinel event program. JCAHO defines a sentinel event as ''an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof.'' Even if each of the accredited hospitals scrupulously and voluntarily reports sentinel events, the 20 percent of Medicare- and Medicaid-participating hospitals that are non-accredited do not provide this information to JCAHO. Since reporting is voluntary rather than mandatory, accredited hospitals may choose not to inform JCAHO. Hospitals may fear that reported information might be used against them in court, which would provide a clear disincentive to consistent and voluntary reporting.

Even if Glass' projection of up to 150 deaths per year is correct, some may question its statistical significance when compared with the number of deaths that result from other factors, such as medical errors. We believe that while deaths are a focal point, it is important not to discount patient injuries. If deaths are under-reported, injury data are even more elusive. Estimating the psychological and social impact of restraint or seclusion is more challenging still. We do not imply that most of the nation's providers recklessly seclude or restrain patients without regard to their emotional well-being. To the contrary, many who commented on this regulation stated that restraint or seclusion are measures of last resort and that they do not undertake these interventions unless absolutely necessary. However, even when a restraint or seclusion is needed, the patient may feel dehumanized, isolated, or depressed as a result. Physical impact, although arguably not simple to measure, is more easily monitored and reported than impact on the spirit.

In summary, we suspect that patient deaths and injuries are underreported, and, even if all parties voluntarily report incidents involving restraint or seclusion or comply with State and local reporting requirements, there are gaps in the system that thwart conclusive calculation of the number of physical injuries and deaths associated with restraint and seclusion use. Given the prevalence of use, the potential for injury, death, or adverse psychological impact, we maintain our original position—that this area deserves regulatory attention to safeguard patient health and safety.

2. The Difference Between Standards (e) and (f)

Comment: Many commenters stated that it is unclear which standard applies in any given situation. One commenter recommended that we delineate a clear, objective explanation of when application of the behavior management standard outside the psychiatric care setting is expected. One commenter objected to the creation of separate requirements for the care of psychiatric patients versus those receiving acute medical treatment, and asserted that all patients should be treated equally. However, most commenters agreed that different requirements should apply to restraints used for violent, aggressive patients as opposed to restraints used in the provision of medical care; some suggested that setting-specific requirements are more reasonable than behavior-specific ones.

Response: Based on public comment regarding the lack of clarity between the application of standard (e) Restraint for acute medical and surgical care, and the application of standard (f) Restraint and seclusion for behavior management, we have revised and combined these requirements into a single standard in the final rule. This combined standard, entitled ''Restraint or seclusion,'' is subparagraph (e) under § 482.12 Patients' Rights in the final rule. This combined standard (e) applies to all uses of restraint or seclusion regardless of the patient's location. Although we have modified some of the provisions to address public comments, these modifications do not lessen protections afforded patients who are restricted or secluded. We note that we have revised the regulation to expand training requirements, and have added a requirement that the attending physician or other licensed independent practitioner (LIP) responsible for the care of the patient be consulted as soon as possible when the one-hour restraint or seclusion evaluation of the violent or self-destructive patient is conducted by a trained registered nurse (RN) or physician assistant (PA).

Comment: A few commenters noted the challenge of making a determination on the standard of care for a patient with multiple diagnoses and behaviors.

Response: We agree that multiple diagnosis and behaviors can make determination on the standard of care a challenge. Therefore, even though several requirements were revised based on public comments, none of the current requirements in standards (e) and (f) have been deleted. All of the requirements contained in the current standard (e) are also contained in the current standard (f). These requirements, in their entirety, have been moved to the combined standard (e) in the final rule. All of the requirements contained in the current standard (f), have also been moved, in their entirety, to the combined standard (e) in the final rule.

Comment: One commenter noted the difficulty in enforcing behavior-specific standards. However, another commenter supported writing the standards to focus on patient behavior or circumstances rather than on the setting. Some commenters requested clarification on what ''behavior management'' means.

Response: For the purpose of clarity we have eliminated the term ''behavior management'' and are using more specific language. The management of violent or self-destructive behavior can occur as part of medical and surgical care as well as part of psychiatric care. The use of the language ''violent or self-destructive behavior'' is intended to clarify the application of these requirements across all patient populations. It is not intended to single out any particular patient population. Based on public comments, we have eliminated the language ''behavior management,'' and have used clearer, more descriptive language in the final rule. Specifically, we have revised the regulations text at 482.13(e) to provide that restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others, and must be discontinued at the earliest possible time. This combined standard clearly outlines the requirements any time restraint or seclusion is used, regardless of the patient's location. We do not support a setting-based approach because interventions and protections provided without considering the patient's behavior and symptoms may fail to adequately safeguard the health and safety of patients. In addition, this standard is not targeted only at patients on psychiatric units or those with behavioral/mental health care needs. The patient protections contained in this standard apply to all patients when

the use of restraint or seclusion becomes necessary.

Although a patient's violent or self-destructive behavior may jeopardize the immediate physical safety of the patient, a staff member, or others more frequently in a psychiatric unit or in a psychiatric hospital, this behavior also appears in the acute medical/surgical care settings, including emergency and critical care settings. Some examples follow. A patient may experience a severe medication reaction that causes him or her to become violent. A patient may be withdrawing from alcohol and having delirium tremors (DTs). The patient is agitated, combative, verbally abusive, and attempting to hit staff. Regardless of facility type, such emergencies generally pose a significant risk for patients and others. For the safety of the patient and others, the use of restraint or seclusion may be necessary to manage the patient's violent or self-destructive behavior that jeopardize the immediate physical safety of the patient, a staff member, or others when less restrictive interventions have been determined to be ineffective to protect the patient, staff, or others from harm. It is not targeted only at patients on psychiatric units or those with behavioral/mental health care needs. The patient protections contained in this standard apply to all patients when the use of restraint or seclusion becomes necessary.

Comment: One commenter suggested adding language in § 482.13(f)(2) to indicate that standard (f) applies when a restraint or seclusion is used, ''In an emergency situation to manage an unanticipated outburst of severely aggressive or destructive behavior that poses an imminent danger to the patient or others.'' Several commenters suggested changing the title of standard (f), examples include, ''Emergency behavior management'' and ''Seclusion/restraint for patients with primary behavioral health care needs.''

Response: The current standard (e) contains two requirements that are more stringent, if restraint or seclusion is used when a patient jeopardizes the immediate physical safety of the patient, a staff member, or others. They are: time limits on length of each order, and the 1-hour face-to-face evaluation. The intent of these more stringent requirements is to add additional patient protections when restraint or seclusion is used for behavior management. We do not intend for these two more stringent requirements to apply to all uses of restraint. We have added clarifying language in the final rule that these requirements apply when restraint or seclusion are used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. We have also specified that seclusion is only permitted to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

Since publication of the interim final rule with comment period, we have repeatedly responded to inquiries regarding the criteria for differentiating between emergency situations where the patient's behavior is violent or self-destructive and jeopardizes the immediate physical safety of the patient, a staff member, or others versus the non-emergency use of restraint. Most of the individuals to whom we spoke indicated that this distinction was clear and understandable. Clinicians are adept at identifying behavior and symptoms, and can readily recognize violent and self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. Asking them to act based on evaluation of the patient's behavior is no different than relying on the clinical judgment that they use daily in assessing the needs of each patient and taking actions to meet those individual needs.

In the final rule, we adopted the restraint definition contained in the CHA. Because the requirements governing the use of restraint or seclusion have been combined in a single standard, we also have a single, consistent definition of restraint. A restraint is any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. The final rule also clarifies that a restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). The devices and methods described above are typically used in medical/surgical care, and would not be considered restraints, and thus not subject to these requirements.

The final, combined standard (e) applies to the use of restraint, the use of seclusion, as well as the simultaneous use of restraint and seclusion. To clarify this point, we have adopted use of the word ''or'' in the final, combined standard for restraint and seclusion. The use of ''or'' imports the ''and,'' whereas ''and'' standing alone requires that both happen. It is not our intent that the requirements in this standard only apply when both restraint and seclusion are used. Therefore, throughout the regulation text, we have deleted ''and'' and inserted ''or.'' The regulations apply to the use of restraint or seclusion. This means they also apply when both restraint and seclusion are used.

3. The Roles of CMS and JCAHO

Comment: Regarding any provision that was not identical to JCAHO's policy, a host of commenters expressed concern that CMS's standards did not parallel or actually ran counter to JCAHO's. One commenter stated that these discrepancies would create an implementation burden for hospitals. A number of commenters expressed concern that CMS was straying from its stated intent of maintaining consistency between Federal and accreditation standards.

Response: In the interim final rule with comment period (64 FR 36079), we stated, ''We believe it is appropriate to recognize JCAHO's work in this area [regarding the length of physician or LIP orders] and maintain consistency between Federal and accreditation standards when possible.'' We adopted JCAHO's standard for time limited orders because, upon examination, we found nothing to suggest that these timeframes have been found faulty or that any more appropriate ones have been scientifically determined. However, we did not intend to suggest that we planned to follow JCAHO's standards in all respects.

Comment: One commenter suggested that the requirement that a physician or LIP see a patient who is restrained or secluded for behavior management within 1-hour is unnecessary because current practice provides good patient care. The commenter cited JCAHO's revision of its standards regarding restraints and seclusion and noted that the hospital agreed with JCAHO and implemented those standards. Further, the commenter reported that the hospital has an ongoing improvement process, which has significantly decreased the use of restraints and seclusion for its adult population.

To govern the use of restraint and seclusion for children, another commenter suggested an approach similar to JCAHO's. The commenter further suggested that national accreditation bodies could establish a certification and approval process for nonviolent intervention regimes. Additionally, the commenter suggested that accreditation surveys or regulatory reviews could include thorough individual and aggregate review of documentation of restraint and seclusion use.

Response: The hospital CoPs are minimum health and safety standards that hospitals must meet to participate in the Medicare and Medicaid programs. The CoPs are intended to protect patient health and safety and to ensure that high quality care is provided to all patients. While we applaud JCAHO's progress in the areas of examining restraint and seclusion use, JCAHO accreditation is voluntary and not the only way hospitals participate in the Medicare and Medicaid programs. Twenty percent of the hospitals that participate in Medicare and Medicaid are non-accredited. Non-accredited hospitals are surveyed by State survey agencies to determine compliance with the CoPs. We have the responsibility to ensure that all Medicare- and Medicaid-participating hospitals have certain protections in place. Before July 2, 1999, the CoPs contained no requirements concerning Patients' Rights.

Our minimum requirements need to exist in regulatory form in order to carry the weight of the law and be enforceable. This final rule informs the public and provider community of our minimum requirements for the protection of patient health and safety while providing a sound basis for legal action if we find that those requirements are not met. While quality improvement initiatives and other internal efforts to track restraints and seclusion use and eliminate inappropriate use are important, we do not believe that they serve as a substitute for stated minimum Federal requirements.

Comment: One commenter stated, ''Let's leave the seclusion and restraint abusers to the civil courts and JCAHO, who are quite capable of creating over-regulations without help from CMS.'' Conversely, another commenter asserted,

''CMS bears a great deal of the blame for the deaths, injuries, and serious long-term psychological harm which those aforementioned patients and their families have endured because it did not amend its CoPs to assure such desirable outcomes. The JCAHO standards were available to CMS during those many years but it chose—for unexplainable and unacceptable reasons—to maintain the status-quo.''

Response: There were other such polarized responses to the interim final rule with comment period. However, many commenters acknowledged the appropriateness of regulation in this area even if they disagreed with individual provisions of the interim final rule with comment period.

The Congress has charged us with creating standards that protect the nation's Medicare and Medicaid beneficiaries and ensure that these beneficiaries receive high quality care. Many commenters came forward with ideas about how the regulation could be changed and improved. Our task is to reconcile these ideas when feasible, and determine the best, most reasonable approach that promotes patient health and safety and yet does not create a disincentive for providers to serve those populations who most critically need their help.

Comment: A commenter stated that CMS's interest in alerting the public to the potential dangers associated with the use of restraint and seclusion is ''faddish.''

Response: This commenter's statement stood in stark contrast to those of many of his contemporaries who wrote of their tireless efforts to avert the potential hazards associated with the use of restraint and seclusion, and of the seriousness with which they undertake such interventions. While accounts of efforts to minimize use of restraint and seclusion and assure patient safety were heartening, a few of the letters we received were disturbing in their conceptualization of a restraint or seclusion not only as wholly appropriate, but as a ''time-honored'' standard of care. To that argument, we reply that standards of care continually evolve. For example, at one time patient shackles were considered a standard intervention. Habit does not justify the continued use of an intervention when alternative methods that are safer or more effective are available. The numerous training programs that emphasize alternative techniques for handling violent or self-destructive behavior and symptoms demonstrate that clinicians recognize the risks inherent in the use of restraint and seclusion. Practitioners in the field of medicine are constantly searching for better ways to manage symptoms and conditions that have been traditionally treated through the use of restraint or seclusion or both. We fully support these efforts.

4. Applicability of the Patients' Rights CoP

Comment: One commenter stated that the preamble should explain the application and effect of the new regulation on psychiatric hospitals. If the regulation applies to psychiatric hospitals, the commenter stated the requirements specified in standard (f) (among others) might not be appropriate.

Response: In the summary of the interim final rule with comment period (64 FR 36070), we explained, ''The Patients'' Rights CoP, including the standard regarding seclusion and restraint, applies to all Medicare- and Medicaid-participating hospitals, that is, short-term, psychiatric, rehabilitation, long-term, children's, and alcohol-drug.'' This final rule, including its provisions concerning the use of restraint and seclusion, is explicitly intended to apply in the psychiatric hospital setting.

We disagree with the opinion that the requirements in the current standard (e) might not be appropriate for the psychiatric hospital setting. While violent or self-destructive patient behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others occasionally occurs on an acute care unit in a hospital, it occurs more often on a psychiatric unit or in a psychiatric hospital. When a patient's behavior becomes violent or self-destructive, the immediate physical safety of the patient, a staff member, or others is at risk. In such an emergency situation, it is critical to ensure that staff is well trained in alternative interventions and techniques; to ensure the safety and well being of the patient and others; to manage the patient's behavior; and, to competently apply restraints or use seclusion. Additionally, the protections provided ensure that: the restrained or secluded patient is appropriately monitored and that the patient's condition is reassessed; the patient's medical and psychological conditions are evaluated; and, the intervention is ended as quickly as possible. Therefore, we believe that the protections in the current standard (f) that have been relocated to the combined standard (e) in the final rule are appropriate for the psychiatric care setting.

Comment: One commenter suggested that we need to develop a separate category of patient rights for children that address their developmental needs rights and other basic needs.

Response: The provisions contained in the Patients' Rights CoP apply universally to all hospital patients,

including children. Although there is no separate category for patient's rights on the basis of age, the regulations recognize differences. Timeframes on orders for the use of restraints or seclusion are different based on age. For example, for children and adolescents 9 to 17 years of age, orders for restraint or seclusion are limited to a maximum of 2 hours. When implementing these regulations, we expect hospitals to develop and implement an approach that meets the individualized needs of the patient populations that they serve.

Comment: One commenter stated that since there are no attending physicians in religious non-medical facilities, amendments should be made to incorporate the provisions of section 1861(ss) of the Act.

Response: Effective January 31, 2000, religious non-medical facilities are not governed by the hospital CoPs, but by their own requirements. The new requirements for religious non-medical facilities do not permit the use of restraint or involuntary seclusion (§§ 403.730(c)(4) and (5)). (For additional information, see the November 30, 1999 and November 28, 2003 **Federal Registers** (64 FR 67028) and (68 FR 66710), respectively).

5. Debriefing After the Use of Restraint/Seclusion

Comment: Many consumer advocates suggested creating a requirement for debriefing staff and patients following each incident of restraint or seclusion, and documenting the use of either procedure in the patient's record. The debriefing's purpose would be to—(1) develop an understanding of the factors that may have evoked the behaviors necessitating the use of restraint or seclusion; (2) give the patient time to verbalize his or her feelings and concerns; and (3) identify strategies to avoid future use of seclusion or restraint. Another commenter recommended that staff debriefing, followed by patient debriefing, occur within 24 hours of each incident of restraint or seclusion. One commenter noted that its hospital requires staff debriefing as part of an approach that has dramatically reduced its incidence of restraint and seclusion use.

Another commenter argued that debriefing is unnecessary in many cases of restraint use. The commenter further stated that requiring debriefing after each use of restraint or seclusion would create unnecessary work.

''It is not uncommon for patients to require restraint or seclusion for multiple episodes of aggression in a 24-hour time period. The underlying rationale for debriefings, to avoid future uses of restraint or seclusion, can be handled by other means, including consultation with the physician or advance practice nurse who authorizes restraint use. There could be debriefings when incidents are critical in nature.''

Response: We agree that debriefing can be a useful, productive exercise that helps both the patient and staff understand what has happened and how such situations can be averted in the future. However, we see the argument made by the opposing commenter as valid. The use of restraint or seclusion is only permitted while the unsafe situation persists, and must be discontinued at the earliest possible time. A patient may have multiple uses of restraint or seclusion in a fairly short timeframe. Requiring that a debriefing occur after each use may be impractical or unnecessary. We believe that hospitals and clinicians will use debriefing as a component of the treatment plan designed to safely manage violent or self-destructive patient behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others as necessary. Therefore, we are not requiring debriefing.

Comment: One commenter suggested that a multidisciplinary team should review each incident within 24 hours. Their review should be part of the hospital's quality assurance and peer review procedures.

Response: We believe that hospitals will monitor restraint and seclusion use through their Quality Assessment Performance Improvement (QAPI) programs. Mandating that a multidisciplinary team review each incident within 24 hours would be unnecessarily burdensome. Therefore, we are not specifying that this must occur in this rule.

B. Comments Received on Specific Provisions

1. The Right To Be Free From Restraint (§§ 482.13(e)(1) and (f)(1))

We stated that the patient has the right to be free from restraints of any form that are not medically necessary, or are used as a means of coercion, discipline, convenience, or retaliation by staff. Section 482.13(f)(1) paralleled this requirement and stated that the patient has the right to be free from seclusion and restraints, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff.

Comment: Many commenters agreed with this general statement and applauded our efforts to eliminate the inappropriate use of restraint. However, some commenters stated that the procedural requirements specified in the interim final rule for the appropriate use of restraint were too idealistic.

Response: We appreciate the support expressed by many commenters. Regarding concerns about the practicality of the current requirements, we believe that some commenters have interpreted current standard to require face-to-face monitoring in every clinical situation. Our intent is that the restrained or secluded patient's condition be assessed and monitored by a physician, other licensed independent practitioner or trained staff at an interval determined by hospital policy. In this final rule, we have amended the regulatory language at § 482.13(e)(10) to reflect this. Hospital policies should address the frequency of assessment and the assessment parameters (for example, vital signs, circulation checks, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity). Hospital policies should guide staff in how to determine an appropriate interval for assessment and monitoring based on the individual needs of the patient, the patient's condition, and the type of restraint used. It may be that a specific patient needs continual face-to-face monitoring; or that the patient's safety, comfort, and well-being are best assured by periodic checks. Continual face-to-face monitoring is only required when restraint and seclusion are used simultaneously to address violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. The hospital is responsible for providing the level of monitoring and frequency of reassessment that will ensure the patient's safety. In this final rule, we have also added language to clarify that a restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

Comment: One commenter stated that he could not find legal authority for health professionals to restrain their patients, absent specific court orders. The commenter also noted that health professionals might be excused for restraining patients only if the purpose of restraint is to minimize an imminent risk of great bodily harm, and only

when the need for restraint is not provoked by the health professional.

Response: We agree that consideration of the safety of the patient, staff, or others is the basis for applying a restraint. We have supported this approach in combined standard (e) by stating that all patients have the right to be free from physical or mental abuse, and corporal punishment, and have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, staff or others and must be discontinued at the earliest possible time. In the final rule, we have also stated that restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm. Finally, we have stated that the type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient or others from harm.

Comment: Several commenters argued that few effective means of therapeutic intervention for significant behavioral problems exist, and that disallowing the use of restraint or seclusion might result in a denial of treatment for individuals with significant problems because of the limitation on what providers can do to address symptoms. These commenters argued that providers would be unwilling to jeopardize staff and others' safety or incur any liability associated with untreated behaviors. Some commenters suggested that this regulation would result in the increased use of other interventions, such as psychotropic medications, to address behavioral challenges. Some suggested that without the use of restraint or seclusion, patients would remain incapacitated by their problems. Several commenters said that CMS inappropriately excluded ''therapeutic'' uses of restraint, such as therapeutic holding and medications.

Response: This final rule does not ban the use of restraint or seclusion. However, it does prohibit the use of restraint or seclusion that are imposed as a means of coercion, discipline, convenience, or retaliation by staff. This final rule also establishes parameters to assure patient safety when less restrictive interventions have been determined to be ineffective to protect the patient, staff, or others from harm. In the final rule, a restraint is any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort. The devices and methods listed here that would not be considered restraints, and thus not subject to these requirements, are typically used in medical surgical care. Although physical holding of a patient for the purpose of conducting routine physical exams or tests is not considered a restraint, all patients have the right to refuse treatment. This patient right is addressed at § 482.13(b)(2). The use of therapeutic holds to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others would be considered a form of restraint and therefore, would be subject to the requirements contained in this final rule. If the definition of restraint is met, then that practice or device (whether it is therapeutic holding or a mechanical device) is considered a form of restraint and may be employed so long as all of the requirements for restraint use are met.

In the interim final rule with comment period, the definition of ''drug used as a restraint'' specifically exempted medications that are used as a standard treatment for the patient's medical or psychiatric condition. Some commenters criticized this definition as being too broad and subjective. This regulation is not intended to interfere with the clinical treatment of patients who are suffering from serious mental illness and who need appropriate therapeutic doses of medications to improve their level of functioning so that they can more actively participate in their treatment. Similarly, the regulation is not intended to interfere with appropriate doses of sleeping medication prescribed for patients with insomnia or anti-anxiety medication prescribed to calm a patient who is anxious. Thus, those medications that are a standard treatment for a patient's condition are not subject to the requirements of this regulation.

In this final rule, we have defined a drug used as a restraint as a drug or medication that is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. We believe this revised definition more clearly supports the role of medications that facilitate the patient's participation in their care and maintenance of the patient's functional status.

Comment: A commenter suggested that the word ''discipline'' should be replaced with ''punishment,'' since the two words are not the same in meaning and there are situations where patient discipline is necessary.

Response: The distinction between the word ''discipline'' and ''punishment'' is a more relevant issue in the developmental disability/mental retardation setting, as opposed to the psychiatric and acute care settings. Therefore, we have retained the use of the word ''discipline.''

Comment: One commenter opined that this regulation provides the ''right to fall and break a hip'' or ''crack your head open.'' Another commenter who provides care to patients with dementia who ''need a vest restraint [commonly referred to as a Posey vest] at night to prevent them from falling out of bed, or getting up and falling in the bathroom,'' questioned whether allowing these patients to fall unnecessarily is more humane than restraining them. The commenter also stated that while some patients can be medicated and restrained briefly on an occasional basis, others—those with dementia or Alzheimers or both, for example, need some type of restraint most of the time on a permanent basis for their own safety.

Response: The final regulation states that devices that protect the patient from falling out of bed are not restraints. However, when the clinician raises all four side rails in order to restrain a patient, (defined in this regulation as immobilizing or reducing the ability of a patient to move his or her arms, legs, body, or head freely) to ensure the immediate physical safety of the patient then the rule applies. Raising fewer than four side rails when the bed has more than two side rails, would not necessarily immobilize or reduce the ability of a patient to move as defined in this regulation.

Practitioners and hospitals utilize a variety of measures to ensure patient safety. Use of a restraint is only one of the possible interventions.

Comprehensive assessment of the patient and the environment, in conjunction with individualized patient care planning, should be used to determine those interventions that will best ensure the patient's safety and well-being with the least risk. However, as part of clinician's decision-making, we would expect such an assessment to be conducted regardless of whether or not the intervention to ensure patient safety is considered a restraint under this regulation. Clinical decision making, which includes assessments, would govern the use of restrictions that are not covered by these requirements.

Regarding the idea that some patients require permanent restraint, we contend that every patient is entitled to an individualized assessment and treatment that takes into account the patient's individual strengths, weaknesses, choices, needs, and concerns. For example, most adults sleep at home in their beds each night without being tied down or otherwise protected from falling out of bed. All use of restrictions, whether governed by these regulations or not, should be based on an individualized patient assessment and the use of all available innovative alternatives and approaches to address patient care needs. Again, we have not prohibited the use of restraints; but we do prohibit using restraints as a substitute for adequate staffing, monitoring, assessment, or investigation of the reasons behind patient behavior such as wandering or getting up in the night, which may be indicative of unmet patient care needs. When the use of restraints is necessary, the combined standard (e) applies.

Comment: One commenter suggested adding the words, ''Or as a replacement for adequate levels of staff,'' to the statement that restraint may not be used as a means of coercion, discipline, convenience, or retaliation by staff.

Response: The final regulation language states that all patients have the right to be free from restraint or seclusion, of any form, imposed for convenience. This language precludes using restraint or seclusion as a substitute for adequate staffing levels. Therefore, we have not accepted this comment.

Comment: One commenter suggested removing the words, ''medically necessary,'' from (e)(1), arguing that physicians would not order treatments that were not medically necessary. Another commenter, however, described just such a case; namely, interventions undertaken at the voluntary request of the patient, such as a cognitively intact patient asking to have his or her bed's side rails put up. This commenter asked if a voluntary request would be exempted from meeting the regulatory requirements.

Response: In the final rule, ''not medically necessary'' has been removed from the definition of restraint. Restraint may only be used to ensure the immediate physical safety of the patient, staff, or others. In addition, a restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

Often with the best of intentions, a patient or the patient's family may ask for a restraint to be applied. For example, a concerned husband may ask that his frail elderly wife be tied into bed to prevent her from wandering. In both examples, the concern may be valid, and a responsive intervention may be appropriate. However, a patient or family member may be unfamiliar with the many innovative, less restrictive alternatives available to address a patient's needs. Such a request, like any other patient or family request for an intervention, should prompt a patient and situational assessment to determine whether an intervention is needed. If a need is confirmed, the practitioner must then determine the type of intervention that will meet the patient's needs with the least risk and most benefit to the patient. A request from a patient or family member for the application of a restraint which they would consider to be beneficial is not a sufficient basis for the use of a restraint intervention. Regardless of whether restraint use is voluntary or involuntary, if restraint (as defined by the regulation) is used, then the requirements of the regulation must be met. Finally, this rule would not preclude a patient, or a patient's family member from requesting that his or her side rail be raised.

Comment: One commenter asked whether the rule requires adding the rights provided by standards (e) and (f) to the hospital's patients' rights policies and procedures and/or a written notification provided to the patient. The commenter argued that specifically stating these rights would require increased staff time, would be a risk management ''nightmare,'' and would require a patient/family member release form to be signed authorizing the use of a restraint, even when a restraint is medically necessary.

Response: Standard (a), Notice of rights, requires patient notification of his or her rights. We are not convinced that notifying the patient of the right to be free from restraint or seclusion imposed as a means of coercion, discipline, convenience, or retaliation by staff, will take significantly more time than informing the patient of his or her other rights, particularly since the hospital retains extreme flexibility in how and when this notice is provided. We are also uncertain why informing the patient of his or her rights would present a risk management ''nightmare.'' Concerning the commenter's third point, the rule does not require that the patient or his or her representative sign release forms. A hospital may choose to introduce this policy; however, depending on the mechanism the hospital uses to provide this notification (for example, as a standard part of each admissions packet; in posted forms in the admissions office or emergency room area; bundled with existing required notices) such a step may be unnecessary.

2. Definition of ''Restraint'' and ''Physical Restraint'' (§§ 482.13(e)(1) and (f)(1))

In the interim final rule with comment period, we stated that the term ''restraint'' includes either a physical restraint or a drug that is being used as a restraint. A physical restraint is any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.

Comment: One commenter recommended uniform definitions of restraint and physical restraint across care settings to avoid confusion. Another commenter suggested defining restraint as, ''the forcible and involuntary deprivation of the liberty to move about.'' The same commenter recommended classifying restraints in three categories: least restrictive (manual restraint or holding); intermediate (seclusion, to be defined as ''restricting voluntary movement by locking a patient in a room. If an individual cannot leave the room at will, the room is considered locked, whether the door is actually locked or not''); and most restrictive and intrusive (mechanical restraints such as belts, cuffs, or soft ties). Several other commenters argued for similar categorization, with corresponding monitoring and ordering requirements

(that is, with consideration for the differences between interventions such as a four-point restraint and a restraint used for frail patients). One commenter argued that physical and mechanical restraints should be defined separately rather than lumped into one category.

Response: We agree that a uniform definition of restraint across care settings is a good approach, adds clarity, and avoids confusion. In the final rule, we have combined the regulations governing the use of restraint or seclusion into a single standard, and have adopted a single, consistent restraint definition. This definition applies to all uses of restraint in all hospital care settings. A restraint is any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. The final rule also clarifies that a restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). This definition renders unnecessary the otherwise impossible task of naming each device and practices that can inhibit a patient's movement.

The concept of liberty of movement as proposed in this comment is incorporated in the final rule at the beginning of combined standard (e). All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to insure the immediate physical safety of the patient, staff, or others and must be discontinued at the earliest possible time.

However, we did not break restraints into three classes or view seclusion as a subset of restraint. We believe that the categorization proposed by the commenter is somewhat arbitrary, particularly in light of the fact that several of the deaths reported by the Hartford Courant occurred during physical holds, which the commenter would have categorized as ''least restrictive.'' This fact makes us wary of suggesting, even implicitly, that physical holds are preferable to mechanical restraint. The deaths resulting from other traditional mechanical devices also persuade us of the hazards of using mechanical restraints. The type of restraint used is not the defining hazard—other variables, such as lack of patient assessment in choosing the restraint, inappropriate application of the physical restraint mechanism or technique, or inadequate patient monitoring could render many interventions dangerous. Accordingly, given the unique circumstances presented by each patient, we believe that it would be inappropriate and would place patients at risk to arbitrarily suggest that one form of restraint is categorically preferable to another.

Finally, we have streamlined and clarified monitoring requirements in combined standard (e). The final rule states that the condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff at an interval determined by hospital policy. When restraint or seclusion is used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen and evaluated face-to-face within one hour after the initiation of the intervention. This final rule provides flexibility for trained staff to determine the monitoring parameters necessary when a restraint or seclusion is used. The more stringent continual monitoring requirements have been retained only for patients who are simultaneously restrained and secluded for management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

Comment: Some commenters asked whether the following constitute restraint: therapeutic holding; comforting children through holding; escorting or touching for de-escalation; virtually any type of touching, like holding a patient's arm to prevent him from hitting the wall; basket holds; or touching to encourage the patient to lie still for a procedure. Many commenters argued that therapeutic holding is necessary, and that the regulation should allow individualized treatment.

Response: Several commenters mentioned different types of holding, including therapeutic holding. For the purposes of this regulation, a staff member picking up, redirecting, or holding an infant, toddler, or preschool-aged child to comfort the patient is not considered restraint. If an intervention meets the regulatory definition of restraint, then that intervention constitutes a restraint and the standards for restraint use must be followed. A restraint is any method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely. A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort. The devices and methods listed here that would not be considered restraints, and thus not subject to these requirements, are typically used in medical surgical care.

The regulation permits the physical holding of a patient for the purpose of conducting routine physical examinations or tests. However, patients do have the right to refuse treatment. See § 482.13(b)(2). This includes the right to refuse physical examinations or tests. Holding a patient in a manner that restricts the patient's movement against his or her will would be considered a restraint. This includes therapeutic holds. Many deaths have involved these practices and may be just as restrictive and potentially dangerous as restraining methods that involve devices. However, the opportunity for individualized treatment of the patient is still available, since the regulation does not prohibit the use of any particular type of restraint. This regulation requires individualized patient assessment and use of the least restrictive intervention when restraint is needed to protect the patient, a staff member, or others from harm.

Comment: Several commenters asked whether a side rail was a physical restraint. One commenter stated that ''the majority'' of hospitals require that side rails be raised for safety reasons, and that patients do not perceive this common safety practice as a restraint. This commenter also cited a need for side rails to be raised to protect patients who are confused or disoriented by narcotics or controlled substances. Another commenter wanted to know if crib rails are a restraint.

Response: The final rule states that a restraint does not include methods that protect the patient from falling out of

bed. It is standard practice to raise the side rails when a patient is on a stretcher, recovering from anesthesia, sedated, experiencing involuntary movement, or on certain types of therapeutic beds to prevent the patient from falling out of the bed. However, the use of side rails to prevent a patient from exiting a hospital bed may pose risk to the patient's safety, particularly for the frail elderly who may be at risk for entrapment between the mattress and the bed frame. A disoriented patient may see the side rail as a barrier to be climbed over or may attempt to wriggle through split rails or to the end of the bed to exit the bed. As a result, this patient may have an increased risk for a fall or other injury by attempting to exit the bed with the side rails raised. The risk presented by side rail use should be weighed against the risk presented by the patient's behavior as ascertained through individualized assessment. Clinical judgment determines whether or not the use of siderails is governed by the rule. When the clinician raises all four siderails in order to restrain a patient, defined in this regulation as immobilizing or reducing the ability of a patient to move his or her arms, legs, body, or head freely to ensure the immediate physical safety of the patient, then the rule applies. Raising fewer than four siderails when the bed has more than two siderails, would not necessarily immobilize or reduce the ability of a patient to move as defined in the regulation.

Regarding the question of whether crib rails are a restraint, placement in a crib with raised rails is an age-appropriate standard safety practice for every infant or toddler. Therefore, placement of an infant or toddler in the crib with raised rails would not be regarded as a restraint. Age or developmentally appropriate protective safety interventions, such as stroller safety belts, swing safety belts, high chair lap belts, raised crib rails, and crib covers, that a safety-conscious child care provider outside a health care setting would utilize to protect an infant, toddler, or preschool-aged child would not be considered restraint or seclusion for the purposes of these regulations. The use of these safety interventions should be addressed in hospital policies or procedures.

Comment: Several commenters believed that mechanical restraints should never be used in the mental health treatment of children and adolescents. One commenter suggested banning both mechanical restraint and seclusion for patients who are 17 years of age or younger. Several commenters offered permutations of this suggestion, such as a ban on the use of mechanical restraint for patients under 17 years of age.

Response: Situations exist where it may become necessary to restrain or seclude a child or adolescent to ensure the safety of the patient or others. Regardless of age, the selection of an intervention must be individualized for each patient. When a restraint is used to manage self-destructive or violent behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, a variety of factors, such as medical condition, disability, psychiatric condition, history of abuse, height, and weight, as well as age, must be assessed and evaluated to determine the least restrictive intervention that will effectively ensure the safety of the patient and others. In unique emergencies, a mechanical restraint may be necessary for a patient under 17 years of age. For example, if a 250-pound 16-year old male is physically attacking another patient, staff may have limited options to stop the attack. At times, the child's size may eliminate the ability to safely use a physical hold with the staff available. The child's medical condition (for example, asthma or a fractured limb) could also contraindicate the use of a physical hold.

However, we recognize that children and adolescents, as well as adults, are vulnerable and at risk when restrained or secluded to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. Therefore, we have retained the time limits on each order for restraint or seclusion to manage aggressive destructive in combined standard (e). Orders are limited to 4 hours for adults 18 years of age or older; 2 hours for children and adolescents 9 to 17 years of age; and 1-hour for children under 9 years of age. The restraint or seclusion order may only be renewed in accordance with these limits for up to a total of 24 hours. Before writing a new order, a physician or licensed independent practitioner must see and assess the patient.

Comment: Many commenters indicated that the restraint definition is too broad and includes items that are typically used in the provision of care, such as catheters, drainage tubes, plastic casts, and bandages, which can restrict freedom of movement. Several commenters asked whether adaptive or protective devices such as helmets, or devices that are used for postural support, meet the definition of restraint. One commenter asked whether CMS would permit the use of devices to assist with chronic conditions or for physically frail patients. One commenter asked that we address the use of restraint for dental, diagnostic, and surgical procedures. The commenter stated that devices used for medical immobilization are given an exemption by JCAHO. The commenter asked if CMS would create a mirroring exemption.

Response: In response to comments, we have added language that limits the application of this definition. In the final rule, a restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). The devices and methods listed here that would not be considered restraints, and thus not subject to these requirements, are typically used in medical surgical care. Adaptive devices or mechanical supports used to achieve proper body position, balance, or alignment to allow greater freedom of mobility than would be possible without the use of such a mechanical support is not considered a restraint. For example, some patients are unable to walk without the use of leg braces, or are unable to sit upright without neck, head or back braces. Such devices generally permit the patient to participate more fully in activities without the risk of physical harm.

Comment: Several commenters suggested that devices used for security purposes should be exempt from the regulatory requirements. Another commenter argued that forensic hospitals or units should be exempted from the regulatory requirements because they compromise the hospital's ability to manage behavior.

Response: The use of handcuffs or other restrictive devices applied by law enforcement officials who are not employees of the hospital for custody, detention, and public safety reasons are not governed by this rule. The law enforcement officers who maintain custody and direct supervision of their prisoner (the hospital's patient) are responsible for the use, application, and monitoring of these restrictive devices in accordance with Federal and State law. However, the hospital is still responsible for providing safe and appropriate care to the patient.

Comment: One commenter argued for the need for ''programmatic'' use of restraint for mentally retarded patients

in a psychiatric or an acute care unit and stated that the interim final rule with comment period created a barrier to using a restraint as part of a treatment plan.

Response: Our expectation is that restraint or seclusion will not be a standard response to a particular behavior or situation. The use of such interventions is a temporary measure that protects the safety of patients and others, but is not a long-term solution for handling problematic behavior.

3. Definition of ''Drug Used as a Restraint'' (§§ 482.13(e)(1) and (f)(1))

We stated that a drug used as a restraint is a medication used to control behavior or restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition.

Comment: Some commenters indicated that the definition of ''drug used as a restraint'' was too broad, subjective, and confusing. One commenter suggested that we adopt the definition of chemical restraint found in the long-term care interpretive guidelines—that is, ''A medication used for discipline or convenience that is not required to treat medical symptoms.''

Several commenters argued that the determination of what constitutes a ''standard treatment'' for certain medical or psychiatric conditions is too subjective. One commenter observed that physicians may legitimately order nonstandard treatments for their patients. Another commenter noted that problems present in mentally retarded patients do not correspond closely to any medical or psychiatric diagnosis and that the rule only discusses these two sorts of standard uses of medication. One commenter explained that in acute care, medications are changed based on the patient's medical condition and symptoms. This commenter also stated that this regulation creates a burden for the administrative staff that will have to distinguish a drug used as ongoing medical management from a drug that, at some point, has evolved into a restraint that is not part of standard treatment.

Other commenters grappled with how to characterize the appropriate role of medications in a patient's care. For example, one commenter expressed alarm at the apparent ban on PRN orders for medications that might affect a patient's behavior or restrict a patient's movement. The commenter argued that medications for behavioral health patients are used precisely to affect behavior so that the patient can participate more fully in his or her care, treatment, and therapy. The commenter stated that they are administered in order to avoid the emergence or escalation of specific behaviors that might prompt the use of more restrictive physical restraints or seclusion. The commenter also stated behavioral health providers recognize that the use of the same drug may be therapeutic in one instance and not in another, and have indicated that a drug used as a restraint should not be applied when its use impedes a person's ability to participate in his or her care. Some commenters noted that drug therapy should be part of an effective treatment plan to manage behavior.

There was little agreement among commenters as to how drugs used to restrain patients should be handled. While a few commenters agreed with the concept that a drug used as a restraint is not a standard treatment (one stating that ''prohibition is critical''), several recommended deleting any reference to a drug used as a restraint. One commenter argued that the use of medications is already closely scrutinized through pharmacy oversight and the physician ordering process. The requirements of the interim final rule with comment period add an unnecessary layer of oversight.

Another commenter stated that the use of a drug as a restraint should appear in its own standard, as the use of a medication differs from physical interventions.

The idea of a medication ''controlling'' behavior garnered considerable comments which included the following:

- All psychotropic medications control behavior to the extent that they reduce psychiatric symptoms;
- The idea of a medication controlling behavior is not as straightforward as it appears;
- No medication ''controls'' behavior. A better word would be ''directs,'' ''contains,'' or ''ameliorates;''
- All drugs have effects as a restraint; and
- The phrase ''control behavior'' should be removed, and a drug used as a restraint should be defined as a drug used with the intent to restrain or restrict the patient's freedom of movement.

One commenter asked for clarification regarding the classification of paralytic drugs, sedatives, and analgesics, and how they would be affected by the regulation.

A commenter suggested that if a patient has consented to the use of a medication, it should not be classified as a drug used as a restraint. Another commenter argued that if a drug is used as a one-time dose to help aid in the plan of care but is not part of the care plan, it is not a drug used as a restraint.

Many commenters characterized the use of a drug as possibly the least restrictive alternative to deal with violent or aggressive behavior, arguing that its use is more humane than allowing the patient to escalate and lose self-control.

Response: Patients have a fundamental right to be free from restraints that are imposed for coercion, discipline, convenience, or retaliation by staff, including drugs that are used as restraints. In the interim final rule with comment period, the definition of ''drug used as a restraint'' was phrased so that medications that are used as part of a patient's standard medical or psychiatric treatment would not be subject to the requirements of standards (e) or (f). These regulations are not intended to interfere with the clinical treatment of patients who are suffering from serious mental illness and who need therapeutic doses of medication to improve their level of functioning so that they can more actively participate in their treatment. Similarly, these regulations are not intended to interfere with appropriate doses of sleeping medication prescribed for patients with insomnia, anti-anxiety medication prescribed to calm a patient who is anxious, or analgesics prescribed for pain management. This language was intended to provide flexibility and recognize the variations in patient conditions.

A standard treatment for a medication used to address a patient's condition would include all of the following:

- The medication is used within the pharmaceutical parameters approved by the Food and Drug Administration (FDA) and the manufacturer for the indications it is manufactured and labeled to address, including listed dosage parameters.
- The use of the medication follows national practice standards established or recognized by the medical community and/or professional medical association or organization.
- The use of the medication to treat a specific patient s clinical condition is based on that patient's symptoms, overall clinical situation, and on the physician's or other LIP's knowledge of that patient's expected and actual response to the medication.

An additional component of ''standard treatment'' for a medication is the expectation that the standard use of a medication to treat the patient's condition enables the patient to more effectively or appropriately function in the world around them than would be

possible without the use of the medication. If the overall effect of a medication is to reduce the patient's ability to effectively or appropriately interact with the world around the patient, then the medication is not being used as a standard treatment for the patient's condition. We believe that trained practitioners possess the skills and abilities necessary to identity when a drug or medication is being used as a standard treatment for the patient's condition and when it is not.

Whether or not the use of a medication is voluntary, or even whether the drug is administered as a one time dose or PRN are not factors in determining if a drug is being used as a standard treatment. The use of PRN medications is only prohibited if the drug is being used as a restraint. The regulation supports existing State laws that provide more vigorous promotion of the patient's choice and rights.

Of course, as with any use of restraint, staff must conduct a patient assessment to determine the need for other types of interventions before using a drug as a restraint. For example, a patient may be agitated due to pain, an adverse reaction to an existing medication, or other unmet care need or concern.

There are situations where the use of a medication is clearly outside the standard for a patient or a situation, or a medication is not medically necessary but is used for patient discipline or staff convenience (neither of which is permitted by the regulation). In such situations, the patient has the right to be free from the use of a drug as a restraint.

For example, a patient has Sundowner's Syndrome, a syndrome in which a patient's dementia becomes more apparent at the end of the day than the beginning of the day. The patient may become agitated, angry, or anxious at sundown. This may lead to wandering, pacing the floors, or other nervous behaviors. The unit's staff find the patient's behavior bothersome, and ask the physician to order a high dose of a sedative to ''knock out'' the patient and keep him in bed. The patient has no medical symptoms or condition that indicates that he needs a sedative. In this case, for this patient, the sedative is being used as a restraint for staff convenience. Such use is not permitted by the regulation. The regulation does not allow a drug to be used to restrain the patient for staff convenience, to coerce or discipline the patient, or as a method of retaliation.

While the characterization of medications as more humane and less invasive was quite common in comments on the interim final rule with comment period, we put forth the caveat offered by one physician—that overuse of antipsychotic medications can result in severe, sometimes irreversible neurological side effects or Neuroleptic Malignant Syndrome, which is potentially fatal. Also increased psychotropic medication use may lead to excessive sedation and cognitive dulling that impairs the patient's ability to benefit from therapy. While medications can be a beneficial part of a carefully constructed, individualized treatment plan for the patient, medication use should be based on the assessed needs of the individual patient and the effects of medications on the patient should be carefully monitored.

We agree with the many comments regarding the idea of a medication ''controlling'' behavior. To further clarify our intent and respond to public comments, we have revised the definition of ''drugs used as a restraint.'' In this final rule, a drug used as a restraint is now defined as ''a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.''

Comment: One commenter asked whether the time-limited orders and the assessment, documentation, and monitoring requirements of standards (e) and (f) apply to a drug used as a restraint.

Response: Yes. If the use of the medication for the patient meets the definition of a drug used as a restraint, the requirements of combined standard (e) apply.

Comment: One commenter asked that orders for PRN medications be deemed appropriate. Many commenters objected to the ban on PRN orders for drugs used as a restraint.

Response: In the final rule, PRN orders for medications are not prohibited. The use of PRN orders is only prohibited for drugs or medications that are being used as restraints. We believe that ongoing assessment, monitoring, and re-evaluation by the ordering practitioner are even more critical when a patient is receiving treatment that is not standard, or is administered in amounts or at a frequency greater than recommended by the manufacturer or current standard of practice, for the patient's condition. Therefore, we are retaining this requirement.

4. Use of Restraints (§§ 482.13(e)(2) and (e)(3)(i))

Section 482.13(e)(2) states that a restraint can only be used if needed to improve the patient's well-being and less restrictive interventions have been determined to be ineffective. Section 482.13(e)(3)(i) states that the use of a restraint must be selected only when other less restrictive measures have been judged to be ineffective to protect the patient or others from harm. These two provisions are redundant, and in the final rule we have collapsed them into one requirement. We will discuss them together, as the public comments tended to apply to both.

Comment: One commenter believed that the regulation should include illustrations of less restrictive interventions and alternative methods for handling behavior, including a requirement that when there is a history of a particular less restrictive intervention being ineffective, other interventions must be tried.

Response: Including such illustrations in the regulation is not feasible. Putting aside the fact that regulations generally provide requirements rather than best practice suggestions, each care situation consists of a unique combination of factors. What seems least restrictive for one patient may not be an appropriate option for another patient. The underpinning of this regulation is the concept that good patient care hinges on looking at the patient as an individual and assessing the patient's needs, strengths, weaknesses, and preferences. Such an approach relies on caregivers who are skilled in individualized assessment and in tailoring interventions to individual patient's needs after weighing factors such as the patient's condition, behaviors, and history. A list of progressive interventions that should be taken would undermine the emphasis on individualized care, and could discourage creativity in meeting patient needs. However, there are resources available. For example, the American Psychiatric Association (APA), American Psychiatric Nurses Association (APNA), and the National Association of Psychiatric Health Systems (NAPHS), with support from the American Hospital Association (AHA), have sponsored the publication of a document entitled, ''Learning from Each Other—Success Stories and Ideas for Reducing Restraint/Seclusion in Behavioral Health.'' This document, published in 2003, was developed through dialogue with the field and extensive input from behavioral healthcare providers throughout the country who have been working to reduce the use of restraint and seclusion, and to improve care within their facilities. To access this document and other useful resources, visit the web sites of the sponsoring organizations:

http://www.naphs.org; *http://www.psych.org*; *http://www.apna.org*; *http://www.aha.org*.

Comment: One commenter argued that it would be impossible to comply both with the Patients' Rights CoP standard (c), which protects patient safety and the patient's right to be free from all forms of harassment, and standard (f). The commenter included the following example, a manic or psychotic patient may be verbally abusive to another patient or destructive of that patient's property without actually being a physical threat to the other patient. The commenter stated that such behavior has often been handled by the use of seclusion until medication can relieve the patient's agitation and abusiveness.

Response: Standard (c) provides that each patient has the right to receive care in a safe setting, and the right to be free from all forms of abuse or harassment. This standard clearly prohibits the behavior described by this commenter, and some type of intervention would be warranted. However, such behavior need not prompt the automatic use of restraint or seclusion. The training requirements in standard (f) of this final rule ensure that patients are attended to by staff that are trained and skilled in utilizing an array of techniques and skills for handling aggression. Depending on this situation, various interventions (other than restraint or seclusion) may address the patient's behavior and simultaneously promote the right of others to safety and freedom from harassment and abuse.

Comment: One commenter suggested that seclusion and restraint should be used only when less restrictive interventions, such as time-outs and one-to-one staffing, are ineffective in preventing immediate injury of the patient or others. Several commenters asked whether less restrictive interventions actually had to be tried and shown to fail before a more restrictive intervention was used. A number of these commenters also questioned whether the patient or another person must be injured before more restrictive intervention may be undertaken.

Response: Less restrictive interventions should be considered before resorting to the use of restraint or seclusion. However, it is not always appropriate for less restrictive alternatives to be attempted prior to the use of restraint or seclusion. For example, when a patient physically attacks another patient, immediate action is needed. When a patient's behavior presents an immediate and serious danger to the patient or others, immediate action is needed. While staff should be mindful of using the least intrusive intervention, it is critical that the intervention selected be effective in protecting the patient or others from harm. Therefore, we have retained the requirement that a restraint or seclusion can only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm.

Comment: One commenter suggested adding, ''The patient has the right to be treated in a safe manner when special procedures are required for the patient's care.''

Response: While we agree that the patient has the right to be treated in a safe manner, we believe that this right exists regardless of whether or not the patient is undergoing a special procedure.

Comment: One commenter suggested considering an issue raised by a New England Journal of Medicine article; specifically, that the regulation should state plainly that a competent patient may refuse the use of physical restraint in the patient's acute care or treatment. The commenter further suggested that an incompetent patient's representative should be able to exercise this right to refuse physical restraint on the patient's behalf. Similarly, another commenter stated that the regulation should consider the individual's right to make choices regarding their health care. The commenter further stated that after complete information is provided about the method, risks, and effects of these procedures, individuals and families should have the right to either reject their use or select them as part of an overall treatment regime.

Response: The Patients' Rights CoP promotes the patient's right to be involved in and make decision about the patient's health care. Standard (b)(2) states that the patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary. In this context, the use of a restraint would be considered a ''treatment.'' Before the patient decides to request or refuse the use of restraint or seclusion, the patient must be informed of the risks associated with refusing the use of a restraint. While the hospital should work with the patient regarding preferences as much as possible, the hospital is not obligated to come up with a menu of alternative options because of the patient's refusal. The hospital may refuse to perform a procedure or render care if it believes that it is unable to safely and appropriately do so because of the patient's refusal to allow certain aspects of the prescribed treatment. In addition, if the patient's violent or self-destructive behavior jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient does not have the right to refuse the use of restraint or seclusion. In this situation, the use of restraint or seclusion is an emergency measure to protect the safety of the patient, staff, or others. If the patient or the patient's representative requests the use of restraint or seclusion, the attending practitioner would need to decide whether the intervention is appropriate.

In conclusion, the restraint or seclusion requirements do not prevent the patient from making informed decisions or participating in the patient's healthcare. The rule establishes the patient's right to be free from inappropriate restraint or seclusion, and lays out basic protections in the event that these interventions are needed.

Comment: One commenter questioned whether, because of the ''Patients'' Rights'' provisions regarding patient privacy and safety, a restrained patient must be restrained in a separate, private room, and not in the day room.

Response: A hazard of restraining a patient is the damage that may be done to the patient's dignity. The patient may feel dehumanized or humiliated, which could be exacerbated by having peers witness the experience. Certainly, we would not expect that a patient put in four-point restraint would be placed in the midst of the day room in a psychiatric facility since this would be humiliating to the patient. The restrained patient should be afforded as much privacy as possible. Since an underlying therapeutic goal for any psychiatric patient is the development of a strong sense of self-worth and dignity, the hospital should take steps to protect the privacy of the restrained patient.

However, an individual wearing mitts to prevent self-mutilating behaviors is also being restricted. These individuals may desire socialization and group activity notwithstanding these restraints that a patient in the midst of a psychiatric crisis would not. We provide these examples to stress that it is critical for the hospital to use an individualized approach that is in the best interest of the patient and promotes

the patient's health, safety, dignity, self-respect, and self-worth.

Comment: Several commenters believed that the documentation of clinical justification for the use of seclusion and restraint, the alternative methods used, and the reasons for their ineffectiveness should be included in the patient's record. Another commenter was concerned that staff's time for direct patient care would be diverted into creating documentation if we require demonstration that less restrictive interventions were proven ineffective in cases that involve medical immobilization.

Response: We agree with the commenters. In the final rule under combined standard (e), we have specified that when restraint or seclusion is used, the following must be documented in the patient s medical record:

- The 1-hour face-to-face medical and behavioral evaluation when restraint or seclusion is used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others;
- A description of the patient's behavior and the intervention used;
- Alternatives or less restrictive interventions attempted (as applicable);
- The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and
- The patient's response to the intervention used, including the need for continued use of the intervention.

We believe that such documentation is a usual and customary recordkeeping practice. This information will provide a valuable tool for charting the patient's course of treatment as well as examining trends of use.

In response to comments, we have added language that limits the application of the restraint definition. In the final rule, a restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). The devices and methods listed here, typically used in medical/surgical care, would not be considered restraints and, therefore, not subject to these requirements. We believe that this addresses the commenter's concern regarding the burden of documentation in such cases.

Comment: Several commenters asked that the word ''determined'' be replaced with the word ''found.''

Response: We consulted the dictionary to determine whether there was some significant difference between these two words. We found none. When we combined the two requirements, we retained the word ''determined.''

Comment: One commenter suggested moving the sentence, ''A restraint can only be used if needed to improve the patient's well-being and less restrictive interventions have been determined ineffective,'' from paragraph (e)(2) to paragraph (e)(1). The commenter stated that this would place a greater emphasis on the fact that less restrictive measures must be demonstrated to be ineffective first.

Response: Although we agree that the language in paragraph (e)(2) is an essential component of standard (e), we do not believe that it is necessary to relocate this language to paragraph (e)(1). We also note that we have revised the regulatory text in the final rule to state that ''a restraint can only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm.'' We deleted the language ''to enhance the patient's well-being'' for clarity.

Comment: One commenter asked which individual(s) would be responsible for making the determination that a less restrictive intervention was ineffective, and suggested that we use the phrase ''clinically determined'' to indicate that this decision would be made by the nursing staff.

Response: Since any trained clinical staff could make such decisions, we have decided not to specify further who should determine that a less restrictive intervention is ineffective for a particular patient.

Comment: One commenter stated that positive reinforcement should be used prior to restraint or seclusion.

Response: Combined standard (e) specifies that restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm. The intent, as suggested by the commenter, is to encourage staff to use alternative, less restrictive methods, such as positive reinforcement, in the patient's treatment.

5. Ordering of Restraint/Seclusion (§ 482.13(e)(3)(ii) and (f)(3)(ii))

In this section, we stated that the use of a restraint must be in accordance with the order of a physician or other licensed independent practitioner (LIP) permitted by the State and hospital to order a restraint. Section 482.13(f)(3)(ii) reiterated this requirement when a restraint is used for behavior management, but added that the use of seclusion must also be in accordance with such an order.

a. Definition of Licensed Independent Practitioner (LIP) (§§ 482.13(e)(3)(ii) and (f)(3)(ii))

Comment: Many commenters stated that the definition of LIP was unclear and open to interpretation. These commenters were unsure of how delegated authority affected whether a practitioner was considered an LIP, of which ''independent'' practitioners qualify as LIPs, and of how the counter-signing of orders affected the determination of whether a practitioner is independent.

Several independently licensed health professionals, such as nurse practitioners and physician assistants, applauded our inclusion of the LIP as recognition of highly trained individuals with strong patient assessment skills. These commenters stated that it was important to recognize the contribution of the multidisciplinary team in today's health care settings.

Many commenters asked for an explanation of who would be considered an LIP. Some commenters wanted explicit recognition of registered nurses as LIPs; one commenter suggested replacing ''LIP'' with the term ''health care professional,'' so that registered nurses would clearly be included. Many licensed professionals such as physician assistants, nurse practitioners and advanced practice registered nurses were concerned that narrow interpretation of the term ''LIP'' might limit their ability to be fully involved in patient care. One organization stated that ''LIP'' is the most problematic language in JCAHO's standards and argued that use of this term might result in inappropriate limits on its constituents' scope of practice. This organization explained that the phrase is given wide and varied interpretations by both hospitals and JCAHO surveyors.

Another concern expressed by commenters was that this regulation marked the first appearance of this term in the CoPs. Several commenters questioned how LIPs might be introduced in the remaining hospital CoPs.

One commenter viewed the term ''LIP,'' with its requirement that the practitioner be able to independently order restraint or seclusion, as restricting existing practice. This

commenter argued that such a restriction should only occur after a finding that the existing practice has had an adverse effect on patient care or that limiting this authority to physicians would improve patient care. The commenter believed that neither the former nor the latter point have been demonstrated or proven. This commenter also noted that State law usually addresses when an LIP may order restraints.

Response: The introduction of an alternative practitioner who could order interventions, assess patients, and renew orders was an attempt to accommodate existing State laws that acknowledge the role of non-physicians in patient care and treatment. We originally used the term ''LIP'' to describe these practitioners to be consistent with existing JCAHO standards.

For the purposes of this rule, a LIP is any individual permitted by State law and hospital policy to order restraints and seclusion for patients independently, within the scope of the individual's license and consistent with the individually granted clinical privileges. This provision is not to be construed to limit the authority of a physician to delegate tasks to other qualified healthcare personnel, that is, physician assistants and advanced practice nurses, to the extent recognized under State law or a State's regulatory mechanism, and hospital policy. It is not our intent to interfere with State laws governing the role of physician assistants, advanced practice registered nurses, or other groups that in some States have been authorized to order restraint and seclusion or, more broadly, medical interventions or treatments.

Each State faces the issue of how to best provide its citizens with access to needed health care services. The issue is complex, as some States have special considerations such as geographic barriers to care delivery, medically underserved areas, and special population needs, all of which would affect how a State resolves this issue. To disregard a State's decision about who is qualified to order medical treatments and interventions and render patient care would be unproductive and arbitrary.

To clarify this, in combined standard (e), we have revised the standard to state that the use of a restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.

b. Physician Only

Comment: While some commenters supported deferring to the States' determination of which health professionals are allowed to order seclusion or restraint, one contingent opposed allowing anyone other than a physician to order restraint or seclusion, evaluate the patient, or renew an order for restraint or seclusion. This group pushed for the rule to override existing State laws that would allow these functions to be performed by anyone other than a physician. Several of these commenters stated that the clinical skills and qualifications of some licensed therapists are not necessarily indicative of an understanding and knowledge of the medical needs or risks of patients in seclusion or restraint. Without this understanding or knowledge, there continues to be risk to patients if other medical symptoms are overlooked.

Some commenters cited national legislation pending at the time that would permit only a physician to order restraint/seclusion. Advocacy organizations charged that by permitting someone other than a physician to order restraint or seclusion, CMS would be allowing any 1 of over 600,000 mental health professionals to authorize the use of restraint and seclusion, effectively undermining the purpose of the rule. Many commenters reminded us that the motivation behind the promulgation of this rule is the increasing concern regarding injuries, deaths or harm associated with the use of restraint and seclusion. One commenter maintained that by significantly narrowing the categories of clinicians permitted to authorize the use, the risk of misuse or overuse of restraint and seclusion would be minimized.

Several commenters cited the importance of physicians' clinical training, the fact that they are individually accountable, and the fact that they are distanced from the daily stress and conflicts that arise between non-physician staff members and patients. Other commenters asserted that it is reasonable to require that only a physician authorize the use of procedures that can have serious and dangerous consequences for patients. A number of factors may lead to a patient displaying violent or agitated behavior, including inappropriate medication, which often times can be corrected immediately. One national organization representing physicians also opposed the recognition of non-physicians as being able to order restraints and seclusion.

Response: Some States have issues such as geographic barriers to care delivery, medically underserved areas, and special population needs. States have handled these difficult issues through a variety of mechanisms. If a State has decided that a group of practitioners may order medications or treatments exclusively, we defer to State laws.

Physicians are individually accountable for the care of their patients. The physician has the discretion to delegate, or to withhold the delegation of, tasks or responsibilities as he or she deems appropriate. We believe that the physician is more than capable of making the determination regarding whether his or her direct oversight is necessary, or whether in some situations, as permitted by hospital policy, these functions can be performed by another practitioner. The continued physician accountability for actions taken under his or her license provides a direct incentive for taking the decision to delegate very seriously.

As commenters pointed out, clinical psychologists or other practitioners who may be authorized by the State to order restraint or seclusion may lack the technical medical skills and training to conduct a comprehensive physical assessment. Therefore, the practitioner who conducts the 1-hour face-to-face evaluation must be able to complete, under their scope of practice, both a physical and psychological assessment of the patient. To ensure physician oversight of restraint and seclusion, we have retained the requirement that the attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

Comment: Some commenters representing independent residential treatment centers, day programs, skilled nursing facilities, and other non-hospital provider types mistakenly believed that the requirements in these hospital CoPs were applicable to them. Accordingly, a number of the commenters cited physician access as a problem.

Response: We reiterate that these requirements apply to Medicare- and Medicaid-participating hospitals only, that is, short-term, psychiatric, rehabilitation, long-term, children's and alcohol-drug hospitals. The pending regulations based on the CHA will address the use of restraint and seclusion in the other settings noted above.

Comment: Several commenters expressed concern that practitioners without psychiatric training may be allowed to order seclusion or restraint to manage aggressive, self-destructive or violent patient behavior.

Response: We have revised combined standard (e) to specify that the use of restraint or seclusion must be ordered by a physician or other LIP who is responsible for the care of the patient and authorized to order restraint or seclusion by hospital policy in accordance with State law. We have also tied the order for restraint or seclusion to the patient's attending physician. The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion. We believe that this modification will alleviate concerns about a practitioner who may not have psychiatric training, or is unfamiliar with the patient's condition or diagnosis providing orders for the patient's care.

Comment: One commenter wrote that when fewer staff at the hospital are allowed to routinely approve seclusions or restraint, there is less likelihood of a serious review and a reduction of their use.

Response: As part of a hospital's QAPI program, we would expect the use of restraint and seclusion to be monitored and evaluated on an ongoing basis. We believe that the number of staff permitted to order restraint or seclusion is irrelevant to the QAPI process.

Comment: Several commenters were concerned that the regulation could be interpreted as precluding physicians enrolled in residency training programs from ordering restraints or seclusion, or from evaluating the need for their continued use. For example, in Maryland, residents generally do not hold a State medical license, but are authorized to practice without completing the usual licensing process. A commenter stated this is permitted because of the close supervision that residents receive during their training, and because required licensing is impractical since residents often move to another State to complete their training or to set up permanent practice.

Response: In many States a resident is authorized by State law to practice as a physician. Therefore, there is no question that a resident can carry out the functions reserved for a physician or LIP by this regulation in accordance with State law.

Comment: One commenter opined that psychologists and behavior analysts, not just physicians, should assume responsibility for the design and oversight of restraint and seclusion. Physicians should regulate chemical restraint and assume principal responsibility for the oversight of psychiatric problems and the design of pharmacological and psychiatric interventions.

Response: We recognize the important role that psychologists and other behavioral health professionals play as members of the multidisciplinary team. We believe that these practitioners should participate in the design and oversight of restraint and seclusion practices, as well as participate in patient care. However, we do not believe Congress gave us the authority to create ordering authority for psychologists or other professionals in States that have not granted them this authority. Wherever State law and hospital policy have afforded ordering rights to these practitioners, we have honored that decision.

Comment: One commenter stated that if the patient or the patient's surrogate voluntarily consents to the use of the restraint in the provision of acute medical and surgical care, an order from the physician or other LIP is not required per JCAHO's requirements. The commenter also stated that if restraints are clinically justified and consent is obtained, the care of the patient is consistent with the standards, and no order should be needed.

Response: The current JCAHO standard at PC.11.40 requires that restraint use be based upon an individual order from an LIP. If an intervention meets the definition of a restraint, the regulatory requirements apply regardless of whether use of the restraint is voluntary or involuntary. This would include the requirement for a physician or other LIP order. The use of restraint is inherently risky. The risks associated with any intervention must be considered within the context of an ongoing process of assessment, intervention, evaluation, and re-evaluation.

c. Elimination of Protocols

Many commenters discussed the key differences between acute medical and psychiatric settings and the use of protocols in specified situations in each of these settings. The more commonly cited examples included the use of arm boards to protect an IV site, or the restraint of a patient's arms to prevent the removal of an endotracheal tube. Commenters argued that in these situations, the need for restraint could be anticipated given the medical procedure or symptoms and condition of the patient. Before publication of the interim final rule with comment period, acute medical and postsurgical protocols were used to handle such situations. Use was triggered by the existence of specified criteria. Some commenters argued that disallowing acute medical and postsurgical protocols increases the risk of needless reintubating or replacement of IVs. Most hospitals use physician-reviewed protocols to determine the need for restraint in the medical/surgical context, a practice that is accepted by JCAHO. JCAHO affirmed this, and recommended allowing the use of protocols in certain situations with medical staff approval. JCAHO explained that during the treatment of certain specific conditions (for example, post-traumatic brain injury) or certain specific clinical procedures (for example, intubation), restraints might often be necessary to prevent significant harm to the patient. For those conditions or procedures, protocols for the use of restraint may be established based upon the frequent presentation of patient behavior that seriously endangers the patient or compromises the effectiveness of the procedures. Such protocols would include guidelines for assessing the patient, and criteria for application, monitoring, reassessment, and termination of the restraint. JCAHO stated that it was unaware of any evidence or studies indicating that the use of protocols in this manner has in any way diminished patient care. Some commenters expressed strong support for these types of protocols.

One commenter stated that we should not prohibit the use of such protocols and the use of PRN orders by LIPs or physicians, and asked that we expressly state that those sorts of protocols are acceptable.

One commenter pointed to a passage in the interim final rule with comment period (64 FR 36083) which discussed the initiation of restraint/seclusion according to protocols developed by hospital and medical staff, as permitting the use of acute medical and surgical protocols.

Response: Protocols are not banned by the regulation. A protocol may contain information that is helpful for staff, such as how a restraint is to be applied and monitored. However, a protocol cannot serve as a substitute for obtaining a physician or other LIP order before initiating each episode of restraint or seclusion use, and the requirements of the regulation must still be met. The philosophy that serves as the foundation for the regulation is that restraint or seclusion use is an exception, not a routine response to a certain condition or behavior. Each patient should be thoroughly assessed. Interventions should be tailored to meet the individual patient's needs. The creation

of a protocol can run counter to this philosophy if it sets up the expectation that restraint will be used as a normal part of care. The use of restraint or seclusion is a last resort when less restrictive measures have been determined ineffective to protect the patient or others from harm, not a standard response to a behavior or patient need.

As discussed previously, we have added language to combined standard (e) that limits the application of the definition of restraint. In the final rule, a restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). The devices and methods listed here, typically used in medical/surgical care, would not be considered restraints and, therefore, not subject to these requirements. This revision clarifies the definition of a restraint and addresses many of the examples cited by commenters.

When implementing a protocol that includes the use of an intervention that meets the definition of a restraint, a separate order must be obtained for the restraint. In addition, the patient's medical record must include documentation of an individualized patient assessment indicating that the patient's symptoms and diagnosis meet use-triggering criteria listed in the protocol. Hospitals that utilize protocols in the situations commenters described would be expected to provide evidence that there has been medical staff involvement in the development, review, and quality monitoring of their use.

d. Initiate versus Order

Comment: Many facilities stated that they do not have a physician present 24 hours a day. One commenter suggested that the registered nurse be given the ability to assess and respond to emergency life threatening situations. Another commenter suggested that we should permit an emergency protocol that could be initiated by a health care professional if a physician or LIP was not present.

Several commenters questioned whether an order would have to be obtained before initiating restraint or seclusion and requested clarification regarding who may initiate seclusion or restraint. One commenter suggested we require that, ''If an order cannot be obtained prior to instituting restraint or seclusion, their use must be authorized by a registered nurse, who shall document in the patient record both the reasons for restraint or seclusion as well as the need to use them prior to obtaining an order.'' One commenter stated that given the unpredictable frequency of emergencies and the need for intervention for certain conditions and populations, requiring a physician's order for each intervention is impractical. Others expressed concern that the regulations do not specifically say that a registered nurse can initiate restraint in an emergency situation, which is most often what happens.

Response: We understand that physicians are not always onsite when an emergency occurs. Registered nurses play a vital role in ensuring patient safety and well being. We do not expect staff to stand by and let the patient injure himself or others without intervening simply because a physician is not present. The hospital may develop emergency procedures that staff follow before obtaining the order for restraint or seclusion; however, an order must be obtained as soon as possible.

Many types of emergencies can occur, and staff are expected to effectively respond. In some emergency situations, the need for a restraint or seclusion intervention may occur so quickly that an appropriate order cannot be obtained before the application of restraints. In these emergency situations, the order must be obtained either during the emergency application of the restraint or seclusion, or immediately after the restraint has been applied. The hospital should address this process in its restraint policies and procedures. These hospital procedures should specify who could initiate the use of restraint or seclusion in an emergency prior to obtaining an order from a physician or other LIP.

6. Prohibition on Standing and PRN Orders (§ 482.13(e)(3)(ii)(A) and (f)(3)(ii)(A))

We stated that an order for restraint must never be written as a standing or on an as needed basis (that is, PRN). Section 482.13(f)(3)(ii)(A) contains a parallel provision for behavior management that also applies to orders for seclusion.

Comment: We received many comments arguing that PRN orders for medication should be permitted. Many commenters, who objected to the PRN prohibition stated that it represents a departure from current practice. Some commenters supported the use of PRN medications as humane and efficacious, in that their administration may help the patient retain self-control and avert escalation of behavior that would require seclusion or physical restraint. These commenters argued that a professional registered nurse is able to appropriately assess and determine the need to administer a PRN. Other commenters argued that PRN medications are not a form of chemical restraint. One such commenter requested that we clarify that orders for PRN medications are appropriate.

One commenter argued that the elimination of PRN medications could inhibit a patient's efforts to manage his/her own behaviors. Another commenter suggested that prohibiting PRN medications might backfire and lead to more routine orders for behavior-controlling medications, with some patients receiving more medication than they would have received with a PRN order. Other commenters stated that they were unsure of how the ban on PRN orders would effect the administration of medications prescribed for agitation.

Conversely, several commenters stated that in their experience, PRN orders are overused for the convenience of staff, and de-escalation techniques are less likely to be attempted in any meaningful manner if such orders are available.

Response: As discussed earlier, the use of PRN orders for medications is only prohibited when a medication is being used as a restraint. A drug is deemed to be a restraint only if it is not a standard treatment or dosage for the patient's condition. Using a drug to restrain the patient for staff convenience is expressly prohibited.

Comment: Several commenters recommended deleting the word, ''written'' from the provision, ''The order must never be written as a standing or on an as needed basis (that is, PRN).''

Response: As we understand it, the commenters' objection to ''written'' is that it fails to acknowledge that orders may be given verbally. Under § 482.23(c)(2), all orders need to be documented in the patient's medical record either manually or electronically. Verbal orders need to be documented in the medical record by the person accepting the verbal order. This regulation does not prohibit the use of verbal orders for restraint or seclusion, but they must be used infrequently. Regardless of whether the order is written by the ordering practitioner or documented as a verbal order, the order may not be written as a standing or on an as needed basis.

Comment: One commenter asked that we replace the word ''must'' with ''shall'' in this section as well as throughout the regulation.

Response: We currently use the word ''must'' rather than ''shall'' in regulations. Both terms mean that the action/activity is mandatory, and as such, the use of ''must'' provides a solid legal basis for enforcement. Therefore, we have maintained the use of ''must''.

Comment: Several commenters indicated that PRN orders for any type of restraint or seclusion should never be used with children or adolescents and that all orders for seclusion should be time-limited based on the individual needs of the youth.

Response: We agree and have maintained these provisions. An order for restraint or seclusion must never be written on a PRN basis. Orders for restraint or seclusion to manage self-destructive or violent behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others must be time limited and should be tailored to the individual needs of the patient. An individualized assessment that considers the patient's characteristics, such as age, history, size, medical and mental condition, and preferences, should be the basis of any intervention. The regulation identifies maximum time limits on the length of order based on age. The physician or LIP has the discretion to write the order for a shorter length of time. The length-of-order requirement identifies critical points at which there is mandatory contact with a physician or LIP responsible for the care of the patient. In addition, the time limits do not dictate how long a patient is in restraint or seclusion. Staff should be continually assessing and monitoring the patient to ensure that the patient is released from restraint or seclusion at the earliest possible time. Restraint or seclusion may only be employed while the unsafe situation continues. Once the unsafe situation ends, the use of restraint or seclusion must be discontinued. In the final rule, combined standard (e) explicitly states that the intervention must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

7. Consultation With the Treating Physician (§§ 482.13(e)(3)(ii)(B) and (f)(3)(ii)(B))

We stated that this order must be followed by consultation with the patient's treating physician as soon as possible if the restraint is not ordered by the patient's treating physician. § 482.13(f)(3)(ii)(B) paralleled that requirement in the behavior management standard, and imposed the same requirement on seclusion if it is used.

Comment: A few commenters suggested that the requirement for notifying the treating physician be deleted. Most comments on this provision revolved around the question of who the treating physician is, particularly when many physicians or specialists are involved in the patient's care. One commenter suggested that the ''treating physician'' should be the physician responsible for the part of care that requires the use of restraint, for example, the pulmonologist would write the order if the patient was on a ventilator. Another commenter indicated that the treating physician for the purposes of an emergency situation after hours is the medical officer on call. Other commenters stated that each hospital should be permitted to determine who the patient's treating physician is.

Response: We agree with the commenters who recommended that hospital medical staff policies determine who is considered the treating (attending) physician. In addition, we have revised combined standard (e) to change the term ''treating physician'' to ''attending physician.'' We do not believe restraint or seclusion use is the only instance where the question of who is in charge of managing the overall medical care of the patient is of concern. Our intent is to ensure that the physician who has overall responsibility and authority for the management and care of the patient is aware of and involved in the intervention. The attending physician information regarding the patient's history may have significant impact on selection of a restraint or seclusion intervention.

Comment: Several commenters asked what was meant by notification of the treating physician ''as soon as possible.'' Most of those who commented on this provision were not in favor of our use of ''as soon as possible.'' One commenter noted that when a restraint or seclusion incident occurs in the middle of the night, it is not realistic to request a consultation with the treating physician. In such a case, the consultation might be delayed 8 hours, possibly longer if ordered on a Friday evening. The commenter was concerned that an oversight review might not consider this standard practice as being ''as soon as possible.'' To clarify this point, the commenter suggested the following wording after ''as soon as possible': ''or the next working day if after hours, if the restraint or seclusion is not ordered by the patient's treating [that is, attending] physician(s).''

One commenter argued that the more familiar the physician present at the time of the restraint or seclusion intervention is with the individual and the treatment plan, the less urgency there would be to obtain the required notification. One commenter suggested incorporating parameters or standards for how quickly this communication must be initiated and accomplished.

Response: The purpose of attending physician notification is to promote continuity of care, to assure patient safety, and to elicit information from the attending physician that might be relevant in choosing the most appropriate intervention for the patient. Therefore, consultation should occur as soon as possible. Hospital policies and procedures should address the definition of ''as soon as possible'' based on the needs of their particular patient population. We have retained the requirement that the attending physician must be consulted as soon as possible if a restraint or seclusion is ordered by a practitioner other than the patient's attending physician.

Comment: One commenter noted that primary physicians often have another physician on call for their patients when they are unavailable, such as during surgery or vacation. In these instances, the physician on call should be considered the treating physician.

Response: We agree. When the attending physician is unavailable and has delegated responsibility for a patient to another physician, then the covering physician is considered the attending physician.

Comment: A commenter indicated that this provision is ''cumbersome and can lead to problems, especially if the treating physician was listed on the admission and does not come into the hospital for twenty-four hours if the patient was admitted on the weekend.''

Response: This provision does not specify that consultation with the attending physician be face-to-face. The consultation can occur via telephone. In addition, when the attending physician is not available, responsibility for the patient must be delegated to another physician who would then be considered the attending physician.

Comment: One commenter asked that we clarify that the patient can be under the care of a treating LIP other than a physician.

Response: The hospital CoPs do permit the patient to be under the care of a treating LIP other than a physician. Section 482.12(c)(1) requires every Medicare patient to be under the care of a doctor of medicine or osteopathy; or

a doctor of dental surgery or dental medicine, a doctor of podiatry, chiropractor, or clinical psychologist within the scope of their license. The individual overseeing the patient's care may be the attending physician or a health professional practicing with the delegated authority or supervision of a doctor of medicine or osteopathy as permitted by State law and hospital policy. As noted earlier, we also defer to State laws that recognize the ordering rights of other types of practitioners. For the purposes of the use of restraint or seclusion, the attending practitioner must be able to conduct both a physical and psychological assessment of the patient in accordance with State law, their scope of practice, and hospital policy.

Comment: One commenter stated that this requirement was highly prescriptive and unusual to be included in a CoP. Another commenter stated that this notification was unnecessary since the treating physician has the opportunity before the need for restraint or seclusion arises to alert hospital staff and other physicians or LIPs that use of restraint or seclusion would be an inappropriate intervention for the patient. These commenters recommended elimination of this requirement.

Response: It is not the information in the medical record alone that should determine the course of treatment for a patient. Decisions about how best to manage a patient's care, engage the patient in treatment, and ensure continued progress in recovery require the oversight of the person with the authority and responsibility for the patient—the patient's attending physician.

8. Written Modification of the Plan of Care (§§ 482.13(e)(3)(iii) and (f)(3)(iii))

We stated in this provision that an order for a restraint must be in accordance with a written modification to the patient's plan of care. A parallel provision in § 482.13(f)(3)(iii) extended this provision into situations where restraint or seclusion is used to manage violent, self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

Comment: Several commenters found this provision confusing and asked for clarification. One commenter was unsure of whether this requirement entails having the nurse explain the patient's behavior in a note, or having the nurse provide a more detailed, written plan. Some of these commenters suggested that the use of seclusion and restraint should not be stated in the patient's plan of care; instead, the behavior(s) that caused the use of seclusion or restraint and other interventions to address the behavior(s) should be documented.

One commenter suggested that as written, this provision indicates that a modification to the plan of care would be required before the order being written for seclusion or restraint. The commenter observed that written modifications might not be possible prior to the renewal of the order because the review and modification should be conducted by the treating physician, while the on-call physician may be involved in assessing an episode of dangerous behavior. This commenter preferred to have a review of the patient's treatment plan within a certain timeframe after the episode, such as the next business day or within 72 hours.

One commenter stated that because restraint and seclusion should be exceptional rather than ordinary interventions, the regulation should incorporate the requirement that multiple restraint and seclusion orders trigger a re-evaluation of the plan of care. Another commenter agreed, recommending that the following language be added at § 482.13(f)(3)(ii)(D):

> Because multiple restraint and seclusion orders may indicate a need to evaluate and change the current placement and/or behavior management plan, where there are two or more restraint and seclusion orders within a one-week period, the chart shall indicate treatment team actions in evaluating the current placement and plan of care and the results of that evaluation.

Response: The regulation does not require that a modification to the patient's plan of care be made before initiating or obtaining an order for the use of restraint or seclusion. The use of a restraint or seclusion intervention should be reflected in the patient's plan of care or treatment plan based on an assessment and evaluation of the patient. The plan of care or treatment plan should be reviewed and updated in writing within a timeframe specified by hospital policy. We have not required that multiple restraint and seclusion episodes trigger a re-evaluation of a placement or behavior management plan. We are retaining the language specified in the interim final rule with comment.

In this final rule, we are specifying that the use of restraint or seclusion be documented in the patient's medical record. In response to comments, we have specified the required elements of documentation under the combined standard. Such documentation is a usual and customary recordkeeping practice. Therefore, we are retaining the language as specified in the interim final rule with comment period.

Comment: Another commenter feared that much detail, such as a description of the event, what led to it, and key data and information typically available to anyone reading the patient's record, will be lost because the provision only requires a written modification to the plan of care. The commenter suggested that facilities would avoid placing such information in the patient's record to assure that the facilities are ''discovery protected.'' To remedy this, the commenter suggested expanding the regulation to require that each instance of seclusion or restraint and certain details must be entered into the patient's record.

Response: We agree. We have revised combined standard (e) to require that the use of restraint or seclusion be documented in the patient's medical record and have specified the documentation elements. Under combined standard (e), the patient's medical record must contain documentation that includes: the 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others; a description of the patient's behavior and the intervention used; alternatives or other less restrictive interventions attempted (as applicable); the patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and the patient's response to the intervention(s), including the rationale for continued use of the intervention. This type of documentation is a usual and customary recordkeeping practice. This information will provide a valuable tool for charting the patient's course of treatment as well as examining trends of use.

Comment: One commenter believed that restraint date, time, and duration should be documented in the patient's record. Another commenter stated that the name, title, and credentials of staff members involved in the procedure should be included in the record.

Response: We have required that when restraint or seclusion is used, certain elements must to be documented in the patient's medical record. We believe that some of the information that the commenter has suggested would indeed appear as part of the patient's medical record. Additional elements of documentation, such as name, title, and credentials of staff members involved in the procedure, should be specified in hospital policy.

Comment: Several commenters recommended removing the word ''written'' from the provision, ''in accordance with a written modification of the patient's plan of care.''

Response: We have retained the word ''written'' in the provision, ''in accordance with a written modification of the patient's plan of care.'' The use of restraint or seclusion constitutes a change in a patient's plan of care. Changes in a patient's plan of care must be documented. Documentation in the patient's medical record can be ''written'' manually or electronically.

Comment: One commenter suggested that the regulations should provide special protections for hearing impaired individuals who communicate in sign language using their hands and arms. To this end, this commenter recommended adding language to § 482.13(f)(3): ''For a person whose mode of communication is through sign language, designed so that the person is able to effectively communicate in sign language despite restraints and/or seclusion.''

Response: Providers are expected to meet the communication needs of their atients, whether those patients speak another language, are hearing or vision impaired, or have other conditions or characteristics that merit special intervention to assure smooth communication. However, there may be situations when it is necessary to place a patient with special communication needs in restraint or seclusion. In these situations, the hospital is expected to make reasonable efforts to meet these needs.

9. Implementation of and Appropriate Use of Restraint/Seclusion (§§ 482.13(e)(3)(iv), (e)(3)(v), (f)(3)(iv), and (f)(3)(v))

We stated that the use of restraint and seclusion must be implemented in the least restrictive manner possible and must be in accordance with safe and appropriate restraining techniques.

No comments were received on these provisions. However, based on inquiries received after closure of the comment period, we have determined that the phrase ''used in the least restrictive manner'' needed further clarification; for example, how would a four-point restraint be used in ''the least restrictive manner''? Our intent is that if a restraint is necessary, the least restrictive intervention (which may vary, depending on the patient's history and condition) that effectively protects the patient's safety or that of others must be selected.

10. Discontinuing the Use of Restraint/Seclusion (§§ 482.13(e)(3)(vi) and (f)(3)(vi))

We stated that restraint or seclusion, whether for acute medical and surgical care or for behavior management, must be ended at the earliest possible time.

Comment: While some commenters expressed support for this provision as written, many hoped to clarify this language and offered either new wording or guiding concepts to be used in developing new wording. Several commenters recommended amending the regulatory text to read, ''Ended at the earliest possible time, namely when no longer needed to ensure the patient's physical safety or whenever a less restrictive measure would protect the patient or others from harm. If restraint and seclusion are used simultaneously, the restraint and seclusion shall be independently evaluated to determine when either or both may be ended.'' A few commenters suggested that restraint use should be ended when it is no longer justified or when the emergency situation has subsided, rather than being dependent on an arbitrary timeframe. One commenter noted that the patient's release from seclusion and his or her rapid return to the therapeutic environment is desirable. Another commenter stated that a patient should be restrained or secluded only so long as necessary for the patient to regain self-control. One commenter noted that if the patient is able to take a bathroom break or eat a meal without incident, the restraint or seclusion should be discontinued. These commenters believed that the regulation did not clearly state that the intervention would end when the emergency was over.

Response: These comments tended to be aimed at standard (f) rather than (e); overall, they seemed to reflect the concern that what constitutes ''at the earliest possible time'' may be subject to interpretation. To address this concern, we have revised the requirement in combined standard (e) to state that restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

Comment: One group of commenters wanted to allow the patient a trial period out of restraints, during which the patient would be closely observed. If the patient again exhibited the symptoms that had prompted the prior use of restraints, the patient would be placed in restraint again and this episode would be considered as part of the original episode/order.

Response: The approach suggested by these commenters is equivalent to a PRN order, which is not permitted by combined standard (e). If staff ends an ordered intervention, they have no authority to start it again without the initiation of a new order. For example, a patient is released from restraint or seclusion. If this patient later exhibits violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others that can only be handled through the use of restraint or seclusion, a new order would be required. Staff cannot discontinue an order and then restart it because that would constitute a PRN order. However, a temporary release that occurs for the purpose of caring for a patient's needs, for example, toileting, feeding, and range of motion, is not considered a discontinuation of the intervention.

11. Assessment, Monitoring, and Evaluation of the Restrained/Secluded Patient (§§ 482.13(e)(4) and (f)(5))

We stated that the condition of the restrained patient must be continually assessed, monitored, and reevaluated. Section 482.13(f)(5) created a parallel requirement when a patient is restrained or secluded for behavior management.

Comment: There was much confusion over the meaning of ''continually.'' One commenter pointed out that ''continually'' appears to refer to constant face-to-face observation in one portion of the interim final rule with comment period, while in another it seems to mean ongoing, but not constant, monitoring. Several commenters misinterpreted the requirement as forcing physicians and nurses to remain in a restrained patient's room for the duration of the restraint use, and argued that this would be a poor use of resources.

Response: Ongoing assessment and monitoring of the patient's condition are crucial for prevention of patient injury or death. We are still requiring these activities, but leave it to staff discretion how frequently they are conducted based upon hospital policy and an individualized patient assessment. In the final rule, monitoring and assessment may occur periodically (for example, every 15 minutes) or continually (that is, moment to moment), depending on the patient's needs. With the exception of the simultaneous use of restraint and seclusion, one-to-one observation with a staff member in constant attendance is not required. To clarify this point, we have deleted the word ''continually'' from the monitoring requirements in combined standard (e) with one exception. We have retained the word ''continually'' in the monitoring

requirements for the simultaneous use of restraint and seclusion.

We expect hospital policies to guide staff in determining appropriate intervals for assessment and monitoring based on the individual needs of the patient, the patient's condition, and the type of restraint used. For example, placing staff at the bedside of a patient with wrist restraints may be unnecessary. However, for a more restrictive or risky intervention and/or a patient who is suicidal, self injurious, or combative, staff may determine that continual face-to-face monitoring is needed. The hospital is responsible for providing the level of monitoring and frequency of reassessment that will protect the patient's safety. Based on public comments, we have revised combined standard (e) to clarify that the condition of the patient who is in restraint or seclusion must be monitored and assessed by a physician, or other licensed independent practitioner or trained staff at an interval determined by hospital policy. The criteria for staff to be considered ''trained'' are specified under § 482.13(f).

We have also added language to clarify that all requirements specified under combined standard (e) apply in the simultaneous use of restraint and seclusion, which is not permitted unless the patient is continually monitored. If restraint and seclusion are used simultaneously to manage self-destructive or violent patient behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be continually monitored, face-to-face, by an assigned, trained staff member; or continually monitored by trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient. For the purposes of this provision, ''continually'' means ongoing without interruption.

Comment: Some commenters requested clarification on the aspects of the patient's physical condition that must be monitored when the patient is in restraint or seclusion (indicators such as vital signs, circulation, hydration, level of distress, agitation), when staff re-evaluate the need for continued use of restraint or seclusion, and when an LIP is deciding whether to renew the order for the intervention. Some commenters also suggested that the patient should be permitted bathroom breaks and the opportunity to eat meals.

Response: The importance of appropriate assessment and monitoring of the patient's physical, emotional and behavioral condition when restraint or seclusion is used cannot be overemphasized. As the interim final rule with comment period stated, research indicates that the potential for injury or harm with the use of restraint is a reality. However, evaluation of the situation and each patient's individual medical needs and health status should be paramount considerations in choosing the intervention method, level of monitoring, and frequency of assessment. Hospital policies should address frequency of assessment and monitoring components of monitoring (for example, vital signs, hydration and circulation, level of distress and agitation, mental status, cognitive functioning, skin integrity), nutritional needs, range of motion, elimination needs, and other care needs. We cannot provide an exhaustive list of the items to be monitored because they will vary with the type of intervention used and the patient's condition. For example, the use of a restraint that keeps the patient immobilized would require a check of the patient's skin integrity and steps to prevent skin breakdown. Depending on the duration of the intervention, range of motion exercises might be necessary. The patient's mental status, as well as vital signs, should be assessed, particularly when the restraint is initiated to manage self-destructive or violent behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. The patient should be provided the opportunity for toileting, hydration, and eating if the intervention used impedes these activities.

Reassessments of the patient's condition are essential to assure that the intervention ends as soon as possible. Again, we expect frequency of reassessments to be addressed by hospital policies. When the patient's self-destructive or violent behavior presents an immediate risk to the patient, a staff member, or others, frequent reassessments ensure the intervention is used only while the unsafe situation continues and is discontinued at the earliest possible time, regardless of the length of time identified in the order.

The interim final rule with comment period did not, and this final rule does not, require that the practitioner who ordered the intervention be physically present to re-evaluate the need for continuing the intervention. The patient's attending practitioner should, however, be contacted with an update on the patient's status and an evaluation of the patient's mental and physical condition when the order for restraint or seclusion is about to expire if it appears that the intervention is still necessary. In this final rule, we have retained and revised the provision under combined standard (e) requiring that after 24 hours, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. We have also specified that each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy.

Comment: A commenter asked what time frames were meant for ''continuously assessed'' (that is, every 5 minutes, every 30 minutes). Some members of the public and one hospital argued that we should incorporate required 15-minute checks for restrained and secluded patients, as we had mentioned in the December 19, 1997 proposed rule. One commenter suggested that vital signs be taken every 2 hours, with written documentation of such checks in the medical record. Some commenters urged retaining flexibility in allowing clinical judgment to determine timeframes or intervals. Some commenters questioned the value of continual monitoring for a restrained patient who is sleeping or only awakening intermittently.

Response: As discussed previously, we expect hospital policies to guide staff in determining appropriate intervals for assessment and monitoring based on the individual needs of the patient, the patient's condition, and the type of restraint used.

Regarding the sleeping patient scenario, a staff person may or may not need to be permanently posted at a sleeping, restrained patient's bedside. The fact that a patient is at one point asleep does not guarantee that the patient will remain asleep hours on end and will therefore need no reassessment or monitoring. The selection of an intervention and determination of the necessary frequency of assessment and monitoring should be individualized, taking into consideration variables such as the patient's condition, cognitive status, risks associated with the use of the chosen intervention, and other relevant factors. In some cases, checks every 15 minutes or vital signs taken every 2 hours may not be sufficient to ensure the patient's safety. In others, it may be excessive or disruptive to patient care (for example, mandating that a patient with wrist restraints who

is asleep be checked every 15 minutes and awakened every 2 hours to take the patient's vital signs may be unnecessary). Similarly, depending on the patient's needs and situational factors, seclusion may require either periodic or constant monitoring. We expect staff to determine the appropriate level of monitoring and frequency of assessment based on hospital policy, an individualized patient assessment, and type of intervention used.

Comment: Commenters discussed who should perform the assessment, monitoring, and re-evaluation. Some mental health consumer advocacy groups and their members suggested that a clinically licensed registered nurse should perform these tasks; another commenter suggested that they be performed by licensed professionals trained in mental health procedures.

Response: We have revised combined standard (e) to provide hospitals flexibility in determining which staff performs the assessment and monitoring. This determination, of course, must be in accordance with the practitioner's scope of practice and State law. For example, assessment and monitoring are activities within a registered nurse's scope of practice. However, some trained, unlicensed staff may perform components of monitoring (for example, checking vital signs, hydration and circulation; the patient's level of distress and agitation; or skin integrity), and may also provide for general care needs (for example, eating, hydration, toileting, range of motion). Standard (f) requires that before applying restraints, implementing seclusion, or performing associated monitoring and care tasks, staff be trained and able to demonstrate competency in the performance of these actions. Combined standard (e) has been amended to require that the condition of the restrained patient be assessed and monitored by a physician, other LIP or by trained staff.

Comment: One commenter suggested that a history of sexual victimization should be considered when restraining a patient. The commenter provided the following example: ''Most females who are raped are raped in the supine position, and therefore supine position is more likely to recreate the trauma. Similarly, it seems that most males who are raped are raped in a prone position, therefore prone restraint might well be contraindicated.''

Response: The hospital should conduct a thorough individualized assessment of the patient that integrates the patient's salient history into the treatment plan. However, we will not be mandating this particular consideration in the regulation's text.

Comment: One commenter urged that children not be left alone for long periods of time, as an hour can seem quite long when a child is distressed. Another commenter argued that children in restraint or seclusion should be monitored one-on-one.

Response: We agree that children, as well as adults, may become distressed when left alone. We expect staff to determine the frequency and level of monitoring necessary based on hospital policy, an individualized patient assessment, and the type of intervention used.

Comment: One commenter suggested that because the lack of vigorous physical activity may contribute to behaviors triggering restraint and seclusion, the regulations should include a section requiring vigorous physical activity for children.

Response: The multidisciplinary team that works with each patient is able to create an individualized treatment plan that meets the patient's needs. We do not believe that arbitrarily mandating vigorous physical activity is wise or necessary.

Comment: One commenter asked how continual assessment, monitoring and reevaluation would be documented.

Response: How this information is documented will vary with the policies and practices of each hospital.

Comment: One commenter asked whether a patient restrained for medical purposes could be monitored from a distance as long as the patient is kept within eyesight.

Response: A patient restrained under combined standard (e) does not have to be continually monitored face-to-face unless restraint and seclusion are used simultaneously or continual face-to-face monitoring is clinically indicated.

12. Staff Training in the Use of Restraints/Seclusion (§§ 482.13(e)(5) and (f)(6))

We stated that all clinical staff that have direct patient contact must have ongoing education and training in the proper and safe use of restraints. Section 482.13(f)(6) contains a similar requirement that specifies that all staff who have direct patient contact must have ongoing education and training in the proper and safe use of seclusion and restraint application and techniques and alternative methods for handling behavior, symptoms, and situations that traditionally have been treated through the use of restraints or seclusion.

Comment: These provisions enjoyed much support from commenters. Several commenters quoted the Hartford Courant series (October 11, 1998) as naming better staff training as a low cost mechanism for averting the situations described in the articles. Many hospitals agreed that the key to patient safety is staff training and competency, suggesting that this element more directly affects patient care than other factors suggested by CMS. One commenter stated the following:

> The death of a patient while in restraints or seclusion should never occur. To that end, steps need to be taken to assure that staff that initiate a restraint or seclusion intervention and those who later monitor and evaluate the patient are appropriately educated, trained, and demonstrate competencies in these practices. We see these issues as key to the safety and well being of patients and staff.

One commenter reported that it provides staff with a minimum of 16 hours of annual training that emphasizes verbal de-escalation techniques. This step, in combination with others, has resulted in dramatic reduction in restraint/seclusion use for that hospital in the past 2 years. Many other commenters reported that their hospitals employ extensive training for clinical staff; one commenter noted that training direct care staff is a good investment of its resources. Another commenter voiced its ''complete agreement'' with the training and educational requirements.

One commenter expressed enthusiastic support for stringent and appropriate training, noting that this area needs to be expanded and enforced. This commenter stated, ''Until service providers are adequately trained in the proper use of restraints, all the regulations and rules in the world will not be able to ensure safety.'' Another commenter suggested that CMS should focus on ensuring that restraint and seclusion are used properly by monitoring training, education, proper privileging, and proper/effective staff monitoring by appropriate and available facility staff.

Response: We appreciate the support expressed by commenters and share the belief that without adequate training and competency among the direct care staff, patients, staff and others are placed at risk. Patients have a right to the safe application of restraint or seclusion by trained and competent staff. We recognize the important role that staff training and education play in the reduction of restraint and seclusion use in a hospital. We applaud hospitals that currently provide extensive training and education for staff as part of a comprehensive program to ensure patient safety and minimize the use of restraint and seclusion.

Based on public comments, we have revised our regulatory language to provide additional requirements for staff training that focus on demonstrated competencies and building a skill set for working with patients. We have also moved the training requirements from current standards (e) and (f), and created a separate standard (standard (f)) that addresses staff training. This was done to emphasize the importance of staff training in the safe use of restraint or seclusion.

Standard (f) requires that staff be trained and able to demonstrate competency prior to applying restraints, implementing seclusion, or performing associated monitoring and assessment of, or providing care for a patient in restraint or seclusion. The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population. Staff must demonstrate competencies as outlined in standard (f) initially, as part of orientation, and subsequently on a periodic basis. Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used by hospitals to address patients' behaviors. Successful completion of training and demonstration of competency must be documented in staff personnel records.

Comment: Many hospitals reported that they have instituted training programs and have made efforts to carefully examine and review their use of restraints. Some argued that such efforts, rather than regulatory standards, are the answer to reducing restraint-related injuries and deaths.

Response: Some of the commenting hospitals stated that they have never had an injury or death related to restraints or seclusion use, and it is appropriate to acknowledge this achievement. As its appearance in our regulation affirms, we believe that a critical piece of ensuring the health and safety of the patient, staff, and others is comprehensive training. However, while training programs are a critical step to assuring patient safety, they do not serve as a substitute for a statement of basic performance expectations.

Comment: One commenter requested that we define, ''direct patient contact.'' Several commenters questioned whether we intended that all staff be trained, including nonclinical personnel or those who have no part in the provision of care (that is, those who would be unlikely to take part in a restraint or seclusion intervention). Some disagreed with a broad training requirement, stating that it would be cost-prohibitive. These commenters argued that the current wording could be construed as including housekeeping staff, service staff, clerical staff, administrative personnel, environmental services staff, dietary staff, laboratory staff, and all clinical staff. Many commenters argued that this level of education should be limited to clinical staff who apply and remove restraints or who provide primary direct care to patients who may require restraints. One commenter suggested that all staff should be trained ''commensurate with the amount of contact with patients'' rather than using direct contact alone as a criterion.

Response: We have accepted the suggestions of these commenters. We have replaced the phrase, ''direct patient contact,'' with more specific language to clarify this requirement. We have revised our standards to require training for the staff who are involved with the application of a restraint, implementation of seclusion, providing care for a patient in restraint or seclusion, or with assessing and monitoring the condition of the restrained or secluded patient.

Comment: One commenter asked whether training would be required for house medical staff/covering psychiatrists.

Response: In the final rule, combined standard (e) specifies that physician and other LIP training requirements must be specified in hospital policy. At a minimum, physicians and other LIPs authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint and seclusion. Hospitals have the flexibility to identify training requirements above this minimum based on the competency level of their physicians and other LIPs and the needs of the patient population that they serve. Physicians receive training in the assessment, monitoring and evaluation of a patient's condition as part of their medical school education. However, physicians generally do not receive training regarding application of restraint or implementation of seclusion as part of their basic education. Depending on the level and frequency of involvement that a physician has in the performance of these activities, the physician or other LIP may or may not require training. If house staff, hospitalists or covering psychiatrists are the medical staff that are directly involved in the care of a patient in restraint or seclusion, a hospital may determine that training is necessary to insure competency of these individuals in this area. We believe the hospital is in the best position to determine if physician training is necessary based on the model of care, level of physician competency, and the needs of the patient population(s) that the hospital serves. Therefore, we have only mandated a minimum level of physician and other LIP training. Instead, we have provided hospitals with the flexibility to specify additional physician and other LIP training requirements, if any, in hospital policy.

Comment: One commenter suggested that staff be required to talk to the patient intermittently to assist the patient's efforts to regain self-control and to explain what the patient needs to do for the restraint or seclusion to end.

Response: The training requirements are intended to equip staff with skills that can be used in this fashion.

Comment: One commenter suggested that there should be Federal compensation for the added cost of providing such training.

Response: Staff training is generally included in administrative costs and is recognized in calculating payments under the hospital inpatient prospective payment system. Therefore, we are not providing separate compensation to fund this training.

Comment: Several commenters asked about the frequency of training. One commenter suggested that the term ''ongoing'' should be replaced with ''annually.''

Response: We have modified the regulatory text to require staff to demonstrate the competencies specified in standard (f) initially as part of orientation and subsequently on a periodic basis consistent with hospital policy. We believe the hospital is in the best position to identify a timeframe for ongoing training based on the level of staff competency, and the needs of the patient population(s) served.

Comment: Commenters had varying ideas about what topics training should cover, and whether the regulation should specify training content in detail. Several commenters asked whether training must be obtained from Federally-specified programs.

One commenter urged that requirements for the training curriculum be described in the regulations. A few commenters suggested that the current standard (f) training requirement should not be limited to the proper and safe use of restraints; one commenter suggested more emphasis on positive behavioral supports and less on ''proper'' use. One commenter supported education on alternatives to restraint use and safe handling of a patient in restraints. Another commenter suggested that the training should include personally experiencing being restrained. One commenter argued that staff should be

trained in values clarification, cultural diversity, and counter-transference since it is commonly acknowledged that patients become more agitated and lose control when staff responds in a manner that provokes the patient.

Response: We have adopted more detailed training requirements in this final rule. In addition, we have moved the training requirements from the current standards (e) and (f), and have created a separate standard (f) that addresses staff training requirements.

Standard (f) states that the hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

- Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of restraint or seclusion;
- The use of nonphysical intervention skills;
- Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition;
- The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);
- Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary;
- Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including, but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation; and
- The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

Staff need to employ a broad range of clinical interventions to maintain the safety of the patient and others in the provision care. The hospital is expected to provide education and training at the appropriate level to the appropriate staff based upon the specific needs of the patient population being served. For example, staff routinely providing care for violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others (such as in an emergency department or on a psychiatric unit) generally require more in-depth training in the areas included in the regulation than staff routinely providing medical/surgical care.

Lastly, we have not required that training be obtained from Federally-specified programs. Hospitals may develop and implement their own training programs or use an outside training program. However, standard (f) specifies that individuals providing staff training must be qualified as evidenced by education, training and experience in techniques used to address patients' behaviors.

Comment: One commenter suggested that training should include instruction on—(1) how to identify patients who may have conditions that would require special attention, (for example, a history of respiratory or cardiac problems); (2) how to monitor patients in restraints; and (3) what conditions are necessary for a person to be released from restraints. This commenter suggested that in standard (f), the training requirement should include instructions on how to screen patients for special problems that could affect the use, type, or duration of restraints (for example, emotional problems associated with a history of abuse or neglect).

Response: We agree and have incorporated the suggested elements in standard (f).

Comment: One commenter suggested that staff that has not completed training should be prohibited by regulation from initiating and complying with orders for restraint or seclusion.

Response: We agree. In standard (f), we require that staff be trained and able to demonstrate competency before applying restraints, implementing seclusion, or performing associated monitoring and assessment of, or providing care for, a patient in restraint or seclusion. Application of restraint or seclusion by an untrained staff member, including contract staff, would constitute a violation of this requirement.

13. Definition of Seclusion (§ 482.13(f)(1))

We defined seclusion as the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.

Comment: Several commenters suggested adding the word ''alone'' to the definition of seclusion. Several commenters pointed out that the definition that appeared in the interim final rule with comment period would define a patient confined involuntarily on a locked unit as being secluded. Additionally, one commenter believed the word ''area'' was too broad and might be read as including being on a unit or ward with others.

Response: In the final rule, we have added the word ''alone'' to this definition for clarity and retained the use of the word ''area''. Seclusion does not include confinement on a locked unit, ward, or other area where the patient is with others. Seclusion is not just confining a patient to an area but involuntarily confining the patient alone in a room or area where the patient is physically prevented from leaving. A situation where a patient is restricted to a room or area alone and staff are physically intervening to prevent the patient from leaving the room or area is also considered seclusion. In addition, we have clarified that seclusion may only be used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

Comment: One commenter stated that physical restraint is more frequently associated with injury and death than is monitored seclusion. This commenter argued against categorizing seclusion with restraint, stating that its use should not be governed by the same requirements. Another commenter said that linking the terms ''seclusion'' and ''restraint'' is misleading in that it creates the inaccurate perception that the two interventions are equivalent in all respects. This commenter could not imagine a death resulting from seclusion, other than from self-inflicted injury (which would indicate a possible need for restraint initially) or from the total and gross neglect of an acutely ill patient, which no amount of regulation would prevent, since this would represent unacceptable, deviant practice.

One commenter stated that seclusion is therapeutically different from restraint. Seclusion is indicated when a patient's behavior poses a significant threat to others or is profoundly disturbing in the therapeutic environment (such as a patient disrobing in public). This commenter suggested that while this behavior is not violent, it is appropriately, humanely, and therapeutically addressed through seclusion.

Response: The frequency and level of monitoring and assessment of the condition of a patient who is in restraint or seclusion are determined by staff based on hospital policy and an individualized patient assessment. These parameters would differ based on the type of intervention used. We would not necessarily expect these parameters to be identical for all types of restraint and the use of seclusion.

In response to the comment about the therapeutic use of seclusion, we note that the use of seclusion is a means to an end, not the end itself. In the example given, simply secluding a patient who habitually disrobes is not a long-term solution to eliminating this inappropriate behavior. The patient should be assessed and engaged in an active, individualized treatment program.

Comment: A commenter, concerned about the needs of students receiving special education, asked whether this regulation would define a child who has been restricted from attending a school program as having been ''secluded,'' and requested that the regulation prohibit this action except when the requirements of the regulation are met.

Response: Not allowing a patient to attend a school program or removing a patient from a classroom setting would not meet the definition of seclusion as defined in this rule, and also outside the scope of this regulation which addresses restraint and seclusion in hospitals.

Comment: One commenter stated that there should be minimum standards for the cubic dimensions and ventilation of a seclusion room, which were not provided in the interim final rule with comment period.

Response: We believe that setting these types of standards is beyond the scope of this rule.

Comment: Commenters concerned with children's issues discussed the use of ''time outs.'' Several commenters argued that CMS should distinguish between seclusion (where a child is locked in a room) and a time out, and that time outs should not be governed by the regulation. These commenters believed that a ''time out'' should be defined as actions to require the child or adolescent to retire to an alternative setting, either in his or her room or in a separate quiet room, but without restraining or locking up the child. Several commenters expressed concern that the regulation prohibits so called ''open door'' and ''decreased stimulation'' time outs, which are used to prevent the escalation of behavior leading to emergency situations. One commenter asked whether a child voluntarily removing himself from a current activity and spending 15 minutes calming his or her emotions constitutes seclusion.

Response: For the purposes of this final rule, seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior. If a patient is free to leave a time out area whenever the patient chooses, this would not be considered seclusion based on this definition. The key distinction in deciding whether an intervention is seclusion or a time out is whether the patient is physically prevented from leaving a room or area. Another distinction is the patient's level of personal control. In the case of seclusion, boundaries are placed on the patient's behavior based on the clinical determination that the patient's behavior poses a risk to the safety of the patient or others. In a time out, the patient is able to respond to staff direction encouraging a time out or to independently decide that such action is needed. In a time out, the staff and patient collaboratively determine when the patient has regained self-control and is able to return to the treatment milieu. In seclusion, this judgment is made by the clinicians—that is, an agitated patient may feel that he or she should be released, even though the patient's behavior continues to be violent or self-destructive.

Comment: One commenter inquired whether seclusion requires a physician's order and all related monitoring and documentation.

Response: The use of seclusion for the management of violent or self-destructive behavior is regulated by combined standard (e). If an intervention meets the definition of seclusion in standard (e), all of the requirements under standard (e) would apply, including those related to a physician or other LIP's order, the 1-hour face-to-face evaluation, monitoring and documentation.

Comment: One commenter expressed concern that the definition of ''seclusion'' covers typical hospital practices, such as keeping visitors and patients out of certain areas for purposes of infection control, security, patient privacy, or prevention of disruption of treatment.

Response: Our modification to the definition, that is, adding the word ''alone,'' should alleviate this concern. In the cases cited, the hospital is keeping patients or visitors out of an area versus involuntarily confining the patient alone within a room or area from which the patient is physically prevented from leaving for management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. It is not the intent of this rule to interfere with hospital infection control practices, security measures, patient privacy or measures intended to prevent the disruption of treatment. Additionally, State law outlines requirements for quarantining a patient. If the need to quarantine a patient arises, the hospital would follow State law. Quarantining, as governed by State law, would not be considered seclusion.

14. Use of Restraint/Seclusion for Behavior Management (§ 482.13(f)(2))

We stated that seclusion or restraint for behavior management can only be used in emergency situations if needed to ensure the patient's, a staff member, or others' physical safety and less restrictive interventions have been determined to be ineffective.

Comment: Many commenters stated that the use of restraint or seclusion is a treatment failure. In contrast, several commenters argued that the regulation's requirements are not guided by solid clinical information, nor do they take into account the realities of inpatient psychiatric treatment. One commenter stated, ''While I am aware of individuals who think that medications and/or restraints for [violent, aggressive] patients should never be applied, such thinking is naïve, unrealistic, and idealistic.'' The commenter recommended that we study how many deaths/injuries/assaults are prevented by appropriate use of restraints.

Response: The role of restraint and seclusion for behavior management was a point of fundamental disagreement among commenters. While we believe that restraint and seclusion are not desirable interventions, we recognize the diversity of patients and situations that clinicians must address. In some of these situations, the patient poses a real safety risk to self or others, and alternative, less restrictive interventions are not sufficient to assure the safety of the patient or others.

Comment: A few commenters strongly agreed that restraints should only be used for emergency safety situations. Some physicians and hospitals indicated that they view restraint as a last resort which is only used when absolutely necessary to protect the safety of the patient or others. One commenter indicated that seclusion and restraint have a valuable place in treatment, but only when used minimally, such as in cases of extreme violence or when needed to protect clients. One commenter stated that the rule does not define the term ''emergency,'' and cited a Maryland regulation that defines an emergency as a situation in which the patient's behavior poses a serious and imminent danger to the physical safety of self or others.

In contrast, a commenter suggested removing ''in emergency situations.'' Another commenter agreed with this

suggestion, arguing that the rule does not permit the use of seclusion and restraint as therapeutic interventions as part of a treatment plan for serious behavioral problems. The commenter argued that although short-term, crisis-based use of seclusion and restraint is necessary, it is not the only appropriate use of restraint, since short-term behavioral restrictions can be the most humane way to prevent the patient from self-injury and reduce the need for invasive medical therapies that can have serious, long-term adverse consequences.

Response: The use of restraint or seclusion should not be a routine response when a patient's behavior begins to escalate. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient or others. Seclusion may only be used for the management of violent or self-destructive behavior of patients when there is an immediate danger of harm to the patient, a staff member, or others. We recognize that there may be circumstances in which the use of restraint or seclusion may be necessary to prevent a situation from escalating into an emergency situation in which a patient is in immediate danger of harming himself, staff, or others. In the therapeutic environment, staff often skillfully intervene with alternative techniques that redirect the patient, engage the patient in constructive discussion or activity, or otherwise help the patient maintain self-control and avert escalation. Therapy is a building process in which the patient gains the skills necessary to appropriately handle daily stressors and situations. The use of restraint or seclusion to manage violent or self-destructive behavior is an emergency measure that temporarily protects the safety of the patient, staff, and others. However, neither restraint nor seclusion is a long-term solution for handling problematic behavior.

Based on public comment, we have clarified this provision by replacing the reference to emergency situations with more descriptive language. Therefore, combined standard (e) states that restraint or seclusion can only be imposed to ensure the immediate physical safety of the patient, staff, or others, must be discontinued at the earliest possible time, and less restrictive interventions have been determined to be ineffective. Seclusion may only be used to manage violent or self-destructive behavior of patients that jeopardizes the immediate physical safety of the patient, a staff member, or others.

Comment: One commenter suggested permitting the use of restraints to control anticipated catastrophic behavior associated with conditions such as Lesch Nyhan Disease (manifested by self-mutilation) or other self injurious or assaultive behaviors. The commenter argued that such use would be appropriate to address intractable behaviors that have not responded to medications or other treatment interventions. This type of use would be part of an individualized plan of care addressing the underlying cause of the behavior and would involve rigorous monitoring and active treatment to allow for the removal of restraints.

Response: The regulation has not barred the use of restraint to manage catastrophic behavior. If a patient has a diagnosed chronic medical or psychiatric condition such as those associated with Lesch-Nyhan Syndrome, and he or she engages in repetitive self-mutilating behavior, the use of restraint would need to meet the requirements of combined standard (e). In these situations where the patient exhibits chronic self-injurious behavior, a PRN order that is applied in accordance with the specific parameters established in the treatment plan would be permitted (note that PRN application of restraint is not otherwise permitted). Again, this use of restraint would need to be integrated into the plan for the patient's care and treatment. As always, the use of alternative interventions should be pursued when feasible, and use of restraint should be discontinued as quickly as possible. Since the use of restraints to prevent self-injury for these types of rare, severe medical and psychiatric conditions have been intergrated into the patient's care and treatment plan, the requirement for the 1-hour face-to-face evaluation and the limitation of length of orders (4, 2, or 1 hour(s) depending on the patient's age) are not applicable.

Comment: One commenter suggested a series of steps for treating a patient who has a known history of assault or who exhibits aggression. First, the patient must have a treatment plan to address the problem. Second, if the treatment plan does not work, a back-up plan must provide the patient relief from whatever seems to be provoking the attack. Third, if the back-up plan fails, staff should try to coach or encourage some alternative to assault. The commenter suggested that assault is almost always goal directed, and that staff's task is to determine the goal and suggest an alternative to achieve it. If alternatives are not accepted, staff should ''reduce their verbiage'' and ''exaggerate simple non-verbal messages.'' If an attack is initiated, staff should continue the use of verbal de-escalation techniques while physically evading attack. If all these interventions fail and the attack continues, ''some form of bodily restraint may be justified.''

Response: We appreciate the commenter's insights. However, the level of detail provided is more typical of hospital policy on how to handle assaultive behavior than of regulatory text. When a patient is exhibiting violent or self-destructive behavior and the patient is in danger of harming themselves or others, and less restrictive interventions have been determined to be ineffective, we expect staff to implement appropriate interventions to ensure the safety of the patient and others. While the steps described by the commenter may be appropriate in some situations, they may not be appropriate in others. For example, a patient is attacking another patient. In this situation, immediate intervention, that is, restraint or seclusion in conjunction with ongoing verbal de-escalation and communication with the patient may be necessary to ensure the safety of all involved. The use of less restrictive interventions that are ineffective in this scenario may, in fact, further jeopardize the safety of those involved. Therefore, it is critical that staff employ the least restrictive interventions that will be effective in ensuring the safety of the patient, other patients, staff and others.

Comment: One commenter observed that insuring the safety of patients (as required by the Patients' Rights CoP) will not be possible unless restraining patients who endanger the safety of others is permitted. The commenter stated that the interim final rule with comment period precludes this type of use of restraint or seclusion. A second commenter agreed, noting that provision (f)(2) of the interim final rule with comment period contradicts (f)(3)(i) in that only patient safety (not that of others as provided in (3)(i)) is mentioned in (f)(2). One commenter suggested the following rewording for (f)(2) to remedy this contradiction: ''Seclusion or restraint can only be used in emergency situations if needed to ensure the patient's physical safety or the safety of others and less restrictive interventions with the patient have previously been determined to be ineffective.'' Other commenters echoed the concern that the requirement should take the safety of other patients and staff into account.

Response: The interim final rule with comment period stated that the use of restraint or seclusion must be selected only when ''less restrictive measures have been found ineffective to protect

the patient or others from harm.'' We have revised the final rule to state that restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm. In addition, we have specified the type or technique of restraint or seclusion used must be the least restrictive that will be effective to protect the patient or others from harm.

Comment: One commenter stated that ''absolute danger'' cannot be the only qualifier for restraint or seclusion use in behavior management. The hospital cited examples of highly agitated behavior that disrupts the treatment milieu, such as a patient yelling profanities, disrobing, or destroying property. In addition, another commenter stated that Maryland regulation permits the use of seclusion or restraint when an individual presents a serious disruption to a therapeutic environment (behavior of such a grave or protracted nature that it significantly interferes with the emotional well-being of other patients or with their treatment).

Response: We recognize that situations do occur in which highly agitated behaviors can disrupt the therapeutic environment. A disruption to the therapeutic environment that jeopardizes the safety of patients, staff, and others could be a situation where the use of restraint or seclusion may be necessary. In these situations, there may be no other intervention short of the use of restraint or seclusion that will assure the safety of the patients, staff and others. Based on these comments, we have revised combined standard (e) to state that restraint or seclusion can only be used to manage violent or self-destructive behavior of patients when they are in danger of harming themselves or others, and less restrictive interventions have been determined to be ineffective. However, we have not accepted the commenter's recommendation regarding ''agitated behavior.'' A patient's agitated behavior may or may not pose a physical safety threat to the patient, staff or others. We caution against automatic responses, where the situation is oversimplified and the intervention is not tailored to the individual patient. For example, the fact that a patient is yelling profanities is not an automatic trigger for restraint use. A patient might yell because of pain or any number of factors, which could perhaps be addressed by other types of intervention. In the examples cited, the patient's behavior should prompt individualized assessment and treatment. A patient who is shouting profanities may be calmed by one-to-one interaction with a staff member. A patient who is trying to destroy an object can, in some cases, be distracted or encouraged to redirect his or her energies. Again, we emphasize that the decision of how to handle any given situation will depend on the patient, the patient's history, the patient's symptoms, and the seriousness and immediate danger presented by the patient's behavior.

Comment: One commenter stated that each patient who is restrained or secluded should be given a complaint form when the intervention ends, with instructions on how to fill it out, and privacy and protection in submitting it.

Response: The hospital is required by standard (a) to establish a process for prompt resolution of patient grievances and must inform each patient who to contact to file a grievance. If the patient or the patient's representative wants to file a grievance, this can be done verbally or in writing.

Comment: One commenter recommended sanctions against providers who misuse or abuse any chemical or physical intervention be significant, sure, and swiftly applied.

Response: We appreciate this commenter's support for vigorous enforcement. Hospital noncompliance with these requirements is of the same gravity as noncompliance with existing standards, and could result in enforcement action.

Comment: A commenter stated that the regulation should reflect the fact that to reduce the use of restraints, it is necessary for hospital leadership to make clear that this is their policy and their goal. The commenter also stated that leadership must create an atmosphere where the use of restraints is not tolerated, unless absolutely necessary.

Response: We agree that hospital leadership plays a critical role in the reduction of restraint and seclusion use. There are many challenges associated with initiating and sustaining reduced use of restraint and seclusion. Strong organizational leadership is essential in creating the culture change necessary to minimize the use of restraint and seclusion. The responsibilities of the governing body and Medical staff are addressed in other CoPs.

15. One Hour Rule (§ 482.13(f)(3)(ii)(C))

We stated that a physician or other licensed independent practitioner must see and evaluate the need for restraint or seclusion within 1-hour after the initiation of this intervention.

This provision was the lightning rod for public comment. Almost every commenting physician opposed the provision as written, and the majority of commenters strenuously objected to it, with most asking that the words, ''see and'' be eliminated to leave only the requirement for a physician or LIP evaluation. A core of commenters from advocacy groups and the general public stated that this provision should be modified by shortening the timeframe to half an hour and eliminating the recognition of an LIP's ability to perform this function.

Many commenters asked what the face-to-face requirement of the interim final rule with comment period accomplished. In the preamble of the July 2, 1999 interim final rule (64 FR 36079) we stated the following:

> In situations where a restraint must be used for behavior management, increased vigilance is required because of the heightened potential for harm or injury as the patient struggles or resists. Furthermore, there is an immediate need for assessment of what has triggered this behavior and for continuous monitoring of the patient's condition. To address the need for quick assessment of the condition, we are specifying that the physician or licensed independent practitioner see the patient face-to-face within 1-hour of the application of the restraint or the use of seclusion.

The one-hour requirement of the interim final rule with comment period was intended to assure patient safety with a quick assessment by a physician or other LIP to rule out possible underlying factors that might be contributing to the patient's behavior, to assess the patient's physical and psychiatric condition, and to decide whether restraint or seclusion continue to be necessary.

Commenters were divided on whether this provision would promote patient safety or address adequately the problems identified by the media. While some commenters stated that deaths that occur during the first hour of restraint or seclusion support the need for this mandated onsite physician or LIP assessment within the first hour, a second group stated that by the time the physician arrived in the 59th minute, if staff were not properly trained, the patient might already be dead. This latter group of commenters argued that our proposed ''fix'' did not directly address the key problem and that we were essentially adding a process without proof of an improved outcome for patients.

Some commenters referred us to a Pennsylvania policy used in its ten State-operated psychiatric hospitals, which requires a physician's face-to-face evaluation within half an hour, and accompanying data that shows a reduction in restraint and seclusion use.

The Commonwealth's policy and data were cited as proof that a half-hour physician face-to-face assessment improves patient care and assures patient safety. In preparing the final rule, we were interested in the Commonwealth's experience, including any outcomes data or research related to its half-hour physician assessment policy. We asked for and received a package of information from the Commonwealth that described its policies regarding restraint and seclusion and data showing use over time.

The Commonwealth's policies provide that—(1) only a physician may order restraint or seclusion; (2) orders may not exceed 1 hour; (3) if a verbal order is given, the physician must physically evaluate the patient within 30 minutes; (4) persons in restraint must be kept under constant observation; (5) each reorder may not exceed 1-hour and requires physical examination; (6) each incident must be followed by patient debriefing; and (7) each use triggers clinical, administrative, and continuous quality improvement review, plus a revision to the treatment plan.

After reviewing the information received, we did not find any claims by the Commonwealth that physician assessment within half an hour had directly contributed to reduced restraint and seclusion use. Furthermore, to make such an attribution would be to ignore the fact that the Commonwealth introduced a multi-pronged approach that embraces many methods to address the issues of patient and staff safety. An important aspect of the approach is that physicians are on staff around the clock in the Commonwealth's psychiatric facilities. The requirements referenced earlier do not exist in isolation, but are part of the Commonwealth's integrated approach and ongoing efforts to work collaboratively toward the goals of restraint and seclusion reduction and patient and staff safety.

To summarize, given the comprehensive restraint and seclusion policies instituted by the Commonwealth, it is simply unclear whether one could point to the half-hour evaluation and demonstrate a direct, causal effect on the reduction in restraint and seclusion initiation and duration in Pennsylvania's State psychiatric hospitals.

Based on our analysis of the information supplied by the Commonwealth, and given the numerous public comments we received on this requirement, we have revised the regulatory language to broaden the types of practitioners who may conduct the 1-hour face-to-face evaluation to include a trained RN or PA unless superseded by State law that is more restrictive. We have also addressed the criteria by which staff are to be considered ''trained'', and specify the components of the 1-hour evaluation. In making these changes, we acknowledge the comments of many psychiatrists and other physicians who noted that they are appropriately consulted within 1-hour of the initiation of restraint or seclusion by the onsite staff. Many such commenters argued that a RN is entirely capable of assessing the patient's condition, and that to suggest otherwise ignores RNs' training and high level of expertise.

How quickly the patient needs to be seen by his or her attending physician (or other practitioner, as noted in the regulation) is left to the medical judgment of the physician or other LIP. We have revised standard (f) to state that if the 1-hour face-to-face evaluation is conducted by a trained RN or PA, the attending physician or other LIP responsible for the care of the patient must be consulted as soon as possible. The attending physician or other LIP is responsible for assuring that the patient receives a timely and adequate face-to-face assessment based on the clinical need presented by the individual patient's case.

Comment: One commenter noted that in California, the contractual relationship between a physician and hospital may affect the hospital's ability to ask physicians to meet the 1-hour requirement.

Response: The comments submitted (some of which came from physicians from California) indicated that a high level of physician involvement in the patient's care already exists. Many reported routine contact with hospital staff if a patient under their care becomes violent or self-destructive and restraint or seclusion may be indicated. Most of these physicians argued for the removal of the word ''see,'' noting that they are willing to be and indeed already are involved with these sorts of decisions, but that their objection was to the onsite visit. We have revised the requirements to permit a trained RN or PA to conduct the 1-hour evaluation, and do not require the physician to come to the hospital to see and evaluate the patient 1-hour after the initiation of the restraint or seclusion. Because this change permits more flexibility and clinical judgment on the physician's part, we believe that the cause for physician objection is largely removed.

a. Comments Objecting to a Physician or LIP Seeing the Patient Within 1 Hour

The majority of commenters objected to our requirement that a physician or LIP see the patient within 1-hour of the initiation of restraint or seclusion for behavior management. They provided the following arguments regarding this requirement as written in the interim final rule with comment period. The rule—

- Is impractical. By the time the physician or LIP arrives, the patient's episode may already be over, leaving some physicians asking what they are supposed to evaluate when they arrive. One physician asked whether he must awaken a patient to perform an evaluation after the intervention has ended if the patient is asleep afterward.
- Forces free standing facilities to hire under qualified and ill-prepared physicians to see and evaluate patients with whom they are unfamiliar.
- Pits the physician against staff.
- Creates hesitation to use an intervention to address violent or aggressive behavior that places the patient, the staff, and other patients at risk. One commenter believed that psychiatrists will tell nursing staff to tolerate aggression or violence until they find time to come and see the patient, which also places those present at the hospital at risk. To provide evidence of the risk to staff, commenters referred to various data sources: the Occupational Safety and Health Administration has named health care workers as one of the most injured-on-the-job occupational groups; the National Institute for Occupational Safety and Health has found that most non-fatal workplace assaults occur in service settings such as hospitals, nursing homes, and social service agencies. Forty-eight percent of nonfatal assaults in the workplace are committed by health care patients; and the Department of Justice has found that mental health professionals rank sixth (behind taxi-drivers, police officers, security guards, prison guards, and bartenders) on a list of occupations with the greatest risk of attack. This requirement, commenters argued, will add risk of on-the-job injury that could otherwise be avoided.
- Inappropriately dictates medical practice. Requiring timely and appropriate medical evaluation is reasonable, but it is not feasible or clinically necessary to require a face-to-face evaluation by a physician in each case. A physician assessment of the situation should always be done, but whether face-to-face evaluation is necessary should be left to the physician's discretion.

• Nullifies the professional clinical decisions of registered nurses and insults their professionalism and training.

• Adversely impacts staff morale, recruitment, and retention. One physician described getting good staff as a continuing challenge since the job is inherently dangerous. He believed that he will lose staff who decide that the increased hassle of inpatient work is not worth the trouble when plenty of outpatient work is available. Other commenters voiced similar concerns, noting that nurses must deal with belligerent and uncontrollable patients, and limiting their available options will make retaining nursing personnel difficult.

• Will cause hospitals to place patients immediately in restraint without trying seclusion (that is, move to the most restrictive intervention first) so that the physician only has to make one visit to assess the patient.

• Will adversely affect patient access to care. Admitting teams will refuse to accept any potentially violent or disruptive patients because of this requirement and thereby increase the number of patients routed to State hospitals, the criminal justice system, or juvenile hall, and increase the number of patients who are put out on the street. Persons with the most severe mental illness will be denied a choice of physicians and hospitals although their treatment needs are the greatest.

• May be impossible to implement. Existing psychiatrist shortages may thwart hospitals' attempts to hire coverage so that this requirement can be met. One facility commented that it has tried to recruit personnel, but was repeatedly told that psychiatrists can make more money with considerably fewer disruptions in their lives by choosing not to do inpatient psychiatry. As a result of these regulations, three of that facility's current physicians are questioning whether they will continue with their inpatient privileges. The commenter also states that a nearby psychiatric unit may close its inpatient services as a result of its entire psychiatric staff resigning. Another hospital reported that no local physicians were willing to be on call and onsite within 1 hour. Many physicians stated that this provision has caused them to question whether they should continue rendering inpatient services.

• Cannot be implemented because of geographical/logistical issues. While large organizations may have house staff and residents with which to meet this requirement, it will be difficult to accomplish in community or rural hospitals.

• May require onsite physicians (usually emergency room physicians) to leave less stable patients simply to comply with this regulation.

• In effect will require all hospitals to have physicians present 24 hours a day, 7 days a week. One hospital noted that hiring an onsite physician would be costly and impractical given the low occurrence of restraint and seclusion.

• Has no clear clinical rationale.

• Will result in patient overmedication in an attempt to avoid such situations. One physician cautioned that overuse of antipsychotic medications can result in severe (sometimes irreversible) neurologic side effects or Neuroleptic Malignant Syndrome, which is potentially fatal. Increased use of psychotropic medications may lead to excessive sedation and cognitive dulling, which could affect the patient's ability to benefit from therapy and other interventions.

• Will be disruptive of care provided to outpatients by requiring that practitioners drop everything to come into the hospital to meet the requirement. This disruptiveness will discourage practitioners from providing inpatient services, and thereby adversely impact patient care and access to good practitioners.

• Is not based in any empirical evidence that suggests that a face-to-face evaluation by a physician or LIP will improve the outcomes of care for patients who are secluded or restrained; nor is it based on any information that suggests that a telephone consultation is less effective than a face-to-face evaluation.

• Will cost too much. Various hospitals provided estimates that ranged from a cost of $62,000 to $750,000 per year. One commenter stated that the economics of small community facilities that provide inpatient psychiatric care are tenuous at best. This regulation may force these facilities to close or go bankrupt. The commenter alleged that we have ''tolled the death knell of inpatient psychiatric services across the country.'' Another commenter believed that most providers will go out of business, and those that remain will have to pass the increased costs on to the payors and patients. One hospital stated that this requirement will force it to ''close its doors.'' One physician reported that nearly all psychiatric facilities and programs operate on a slim margin at best. Studies have shown that mental health program budgets have been reduced by 54 percent over the past decade, compared to 7 percent in non-psychiatric medical programs. Programs that specialize in treating geriatric and juvenile patients will be severely affected by this rule. It is likely, he argued, that administrators will be forced to divert resources for staffing levels, equipment, patient education, case management, and other critical patient care activities to offset the cost of implementing the rule. One hospital sent in a notice of closure as a comment.

• Will be costly, both in time and resources. Each time the physician is required to see a restrained/secluded patient, there will be an additional fee for the visit. Most often, a physician who is unfamiliar with the patient will have to spend time reading the chart and examining the patient, and talking to staff. This may also result in confusion about treatment.

• May be used to manipulate the physician since the patient can escalate his/her behavior, knowing that the physician will have to appear within 1-hour as a response.

• Will be ignored by the medical community. One physician indicated that the unanimous response he has received from colleagues is that ''it ain't gonna happen.''

• Does not allow for treatment that is individualized and based on medical necessity.

• Is unreasonable. Physicians in independent private practice have full out-patient office schedules after hospital rounds and cannot be expected to cancel an entire schedule and ignore the clinical needs of outpatients to drive to the hospital on an unpredictable and irregular basis. Family practitioners and specialists have a full daytime schedule and will not be able to provide quality services if they are exhausted and unpredictable in their schedules.

b. Comments Supporting Telephone Consultation With a Nurse Onsite Performing the Patient Assessment

Many of these commenters suggesting deleting the word ''see'' from the requirement to allow staff consultation with the physician or LIP by phone. A large number of these commenters agreed with the revised language proposed by the American Hospital Association (AHA) and the National Association of Psychiatric Health Systems (NAPHS), ''A physician or other licensed independent practitioner must evaluate the need for restraint or seclusion within one hour after the initiation of this intervention.'' AHA and NAPHS believed that the evaluation may be done by the physician or LIP in consultation with a registered nurse who has demonstrated competency in the evaluation of a patient in restraint or

seclusion and who is in face-to-face contact with the patient. Many commenters argued that this change would be appropriate because qualified registered nurses are more readily accessible in emergency situations. Because of the RN's involvement at the earliest stages of an event, the RN would be able to provide additional information about the situation and provide the physician with rapid, appropriate consultation. The RN would carry out the physician's order and direct staff in the use of least restrictive methods and in the discontinuation of restraint or seclusion at the earliest possible time, as specified in the interim final rule with comment period.

The NAPHS further suggested that the content of the nurse/physician consultation include the following elements in order to promote an informed evaluation of the patient: (1) Consideration of organic causes for the behavior; (2) known medical disorders; (3) the patient's medications; (4) the patient's mental status; (5) a brief neurological examination; and (6) vital signs. If data from this evaluation supported the need for a face-to-face visit, then the physician would come to see the patient.

Other commenters argued that by limiting the ability to assess the patient to an LIP or physician, CMS is contradicting JCAHO standards which permit a RN to assess and document the need for restraint. Many commenters supported RN or psychiatric nurse assessment of the patient.

One commenter noted that the interim final rule with comment period permitted the evaluation to be performed by ANY physician, even one with no training in psychiatry and no direct knowledge of the individual's medical and treatment history—but would not permit the evaluation to be conducted by a psychiatric nurse or other licensed professional who is an integral part of the patient's individual treatment team. This organization urged CMS to ensure that orders for these interventions and evaluations following initiation of the interventions be conducted by licensed practitioners who are specially trained and qualified to assess and monitor both the inherent medical and the psychological risks. This may involve physicians or LIPs, or nurses or psychologists who are more familiar with the individual's psychological history. Another commenter echoed this concern, arguing that non-psychiatric physicians do not necessarily have the competencies for treating people with mental illness.

One commenter interpreted the rule to inappropriately devalue and undermine the profession of psychiatry, as well as psychiatric care, by requiring face-to-face assessment for psychiatrists, but not for other physicians. This commenter asked whether physicians who are not psychiatrists have greater reasoning ability and better judgment in matters that involve assessing the appropriateness of restraint and seclusion, or whether nurses in medical hospitals are somehow more adept at reporting reliable and accurate information to treating physicians than those nurses who work in psychiatric hospitals. The commenter also supported the use of telephone consultation.

A commenter stated that the requirement would in all probability be unproductive. The commenter also stated, ''Patients requiring seclusion or restraint have shown behaviors potentially dangerous to themselves or others; such behaviors are caused by impaired reasoning, distorted thinking, or other irrational stimuli. It is extremely unlikely that such an event would have resolved in an hour; either the patient would continue to be irrational or would be sedated from concomitant therapeutic use of medication so that an assessment would not be possible.'' The commenter stated that telephone contact between staff and physician is perfectly adequate. In addition, the commenter noted that an appropriate review of the circumstances is much more likely several hours (8 to 12) after the initiation of the intervention.

A few commenters' disagreements were based on the idea that episodes requiring restraint and seclusion typically involve such gross behavioral problems that they cannot be mistaken for anything other than emergencies, so a physician's visit to assess the need for restraint is not essential. A commenter who had experience in a hospital with a 2-hour face-to-face rule reported that he has never disagreed with a nurse's assessment that a given patient needed to be restrained.

One commenter pointed out that the physician is always accountable for the medical care his or her patient receives, as well as for what actions are taken under his or her direction or license. Another commenter noted that since the order has already been implemented, the physician has already accepted responsibility, so requiring face-to-face evaluation is unnecessary.

c. Comments Opposing Telephone Orders, Nurse Evaluation, and Other LIP Involvement

Some commenters strongly disagreed with allowing telephone orders for restraint and seclusion and with allowing anyone other than a physician to perform the face-to-face evaluation of the patient. One commenter, an RN/PhD, made the following statements:

> This letter comes to urge members of the regulatory task force to require that physicians complete a face-to-face assessment of the patient within the hour after initiation of the restraint or seclusion and every hour thereafter. There are many reasons for a patient to become ''out of control,'' among which are reactions to medications, delirium secondary to metabolic dysfunction, hypoxia, and so forth. These need to be assessed thoroughly and with all due respect to my own profession [the commenter is a RN and Ph.D.], most practicing nurses are not educationally equipped to make such evaluations. In my years of practice, I have seen patients placed in restraints when they had akathesia and when they were confused as a result of impending pulmonary edema with nurses labeling this as ''out of control.'' In fact, I had opportunity to render an expert opinion in a lawsuit involving the death of a gentleman who died in congestive heart failure—he was hypoxic, became confused, and the nurses tied him down. It is not a pretty thought that he drowned in his own fluid tied to a bed.

Similarly, another commenter wrote,

> Sometimes it is important for us to do what is right instead of what is convenient. For the last 40 years that I can remember, we have looked for easy ways to restrain uncooperative patients without infringing on our own time and effort. There is no proper way to do it. One hour of restraint or seclusion is certainly a maximum that should be allowed before personal examination and evaluation by someone who is authorized to directly give such an order. Think of the patient, a decent human being, not yet properly evaluated for the patient's ''bad'' or ''uncontrollable'' behavior. One hour is a long time to be physically restrained for no or improper reasons. The time allotted to a temporary restraining order must be minimal. The person providing the evaluation and giving the regular order must do so very quickly thereafter and be able to accept responsibility for doing it without proper indication. There will be a lot of opposition to this position, as there has been continuously ever since these treatments were first used. But that does not make it right to use them improperly. There is no other way to treat our fellow men and women.

d. Comments Stating That the 1-Hour Provision Did Not Address the Problem

Other commenters took issue with the idea that the requirement for a physician's onsite visit would prevent the sorts of situations described in the Hartford Courant's series. A physician who serves as an expert consultant to Protection and Advocacy, Inc. has reviewed several cases of deaths occurring in chronic and acute care facilities. He stated,

Several of these deaths occurred among patients who were at the time of their death contained (or in the process of being contained) in seclusion or restraints. These deaths were tragic and in some cases due to serious, preventable errors. However, I do not believe that the outcome in any of these cases that I have reviewed would have been changed by the proposed rule that patients requiring seclusion or restraint be evaluated face-to-face by a physician or LIP within one hour after the initiation of these interventions.

Many facilities that opposed the provision reported having had no injuries or deaths associated with restraints use. Many discussed their use of training programs to assure staff competency and argued that training and monitored staff competency, not the 1-hour requirement for a physician's onsite visit, was the key to assuring patient safety.

Many commenters argued that better training in restraint use, constant or frequent monitoring of patients in restraints, the banning of dangerous techniques such as face-down floor holds, and CPR training for all direct care workers could prevent the deaths associated with restraint use. One hospital reported that during a recent three-month period, it identified 94 patients who would have been covered by the 1-hour provision. Of these 94 cases, no restraint-related injury occurred.

Some commenters believed that this provision was excessive and unnecessary, given that they had no problems with deaths or injuries caused by restraint.

Another commenter argued that the problems that have caused the reported deaths and injuries have been due to the administrative policies of the problematic facilities. The commenter therefore believed that it is unnecessary to develop new rules to cover a ''problem'' that for the most part does not exist. Another commenter affirmed this point, stating,

Several years ago, the California Psychiatric Association investigated the causes of deaths of persons who had died in seclusion and/or restraint in California over a period of several years. Our investigation found that in nearly every case, the seclusion and/or restraint was in violation of the hospital's own policies and procedures. The better answer to seclusion and restraint deaths is enforcement of existing laws, not the enactment of a law which will have the unintended consequence of denying the sickest of the sick hospitalization.

One commenter characterized this requirement as, ''A very arbitrary decision and obviously made without much thought at all.'' The commenter further stated, ''While there have been instances of deaths, to make an unreasonable demand upon all physicians because of a few instances that can be corrected is extremely unreasonable and would greatly change how psychiatrists and physicians practice medicine in a negative way and would not add anything positive in terms of health care. Hospitals and physicians will work hard with CMS to eradicate such abuses as have been reported.'' Another commenter agreed, stating the following:

While it is desirable to remedy the shortcomings of our current restraint and seclusion practices, it is immediately apparent to me that your new requirement will result in more patient injuries because of the difficulty of compliance with the new standard. Since you are demanding a new type of treatment protocol, I suggest that the burden is yours to demonstrate in a controlled trial that your solution will indeed be more effective than the existing policy. This is the same process by which all proposed therapies are judged in our field. To do less is to subject all patients to a cruel mass experiment.

One hospital agreed with many of the points raised by CMS in the interim final rule with comment period, and with the position of the National Alliance for the Mentally Ill (NAMI), and supported standards that protect people with mental illness from abuse or unnecessary risk. The hospital noted that it has adopted most of NAMI's best practices initiatives in their institution. However, the hospital stated this provision provides no additional benefit to the patient and may cripple its ability to provide a high standard of care to its patients.

Response: The revised requirement in no way prohibits a physician from coming to the hospital to assess the patient in person. In the final rule, combined standard (e) requires that if a trained RN or PA conducts the 1-hour face-to-face evaluation, the attending physician or other LIP responsible for the care of the patient must be consulted as soon as possible after completion of the evaluation. As many commenters noted, telephone consultation may be effective in this context. Other steps may be critical in addressing the problems identified in the Hartford Courant series. We are not persuaded that it is practical or necessary in all cases for a physician to physically be present within 1-hour to assess the patient. We believe that the patient's attending physician or other LIP responsible for the care of the patient is sufficiently qualified to determine whether the patient's symptoms, condition, and history indicate the need for an immediate onsite visit.

Based on the arguments and information submitted by the commenters, we have revised these requirements. When restraint or seclusion is used to manage violent or self-destructive behavior, a physician or other LIP, or a RN or PA trained in accordance with the requirements specified under § 482.13(f), must see the patient face-to-face within 1-hour after the initiation of the intervention to evaluate: (1) The patient's immediate situation; (2) the patient's reaction to the intervention; (3) the patient's medical and behavioral condition; and, (4) the need to continue or terminate the restraint or seclusion. As is the case with all CoPs, States are free to have requirements that are more restrictive than these requirements. For example, States have the flexibility to limit who may conduct the 1-hour face-to-face evaluation, require that the evaluation be completed in less than an hour, or require additional training. Finally, if the 1-hour face-to face evaluation is conducted by a trained RN or PA, the attending physician or other LIP who is responsible for the care of the patient as specified under § 482.12(c) must be consulted as soon as possible after completion of the 1-hour face-to-face evaluation.

Comment: One commenter suggested that the psychiatrist be thoroughly informed of the events that led to the need for an intervention, vital signs, and other pertinent clinical information by telephone, and be required to conduct the onsite evaluation ''within a reasonable time, not to exceed two hours.'' This wording, the commenter noted, will allow some flexibility without completely abandoning time limits.

Response: We agree that the attending physician (psychiatrist) should be kept informed about the patient's status. The final rule specifies that the attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion. It also specifies that the attending physician or other LIP responsible for the care of the patient must be consulted as soon as possible after the completion of the 1-hour face-to-face evaluation if this evaluation is completed by a trained RN or PA. During these consultations, we would expect that the patient's status and areas suggested by the commenter are discussed with the attending physician. We do not believe that it is necessary to require that the attending physician conduct an onsite evaluation within 2 hours. How quickly the patient needs to be seen by his or her attending physician (or other practitioner, as noted in the regulation)

is left to the medical judgment of the physician.

Comment: One commenter noted that under Commonwealth of Virginia law, only physicians and licensed clinical psychologists are able to order restraint and seclusion. The commenter stated that the recognition of LIPs in this provision did nothing to lessen the facility's burden.

Response: This regulatory provision is applicable unless superseded by State law that is more restrictive. It is not our intent to interfere with State laws governing who may order restraint and seclusion.

Comment: Some commenters argued that licensed practitioners such as social workers and psychologists (who may be recognized under some State laws as being LIPs) do not have training in physiology or pharmacology and therefore may not be able to assess the patient appropriately in an emergency situation.

Response: In this final rule, we have specified that while these types of practitioners may order restraint or seclusion if permitted to do so by State law and hospital policy, the patient's attending physician (or other practitioner) must be contacted to assure continued medical oversight and continuity of care. The 1-hour face-to-face evaluation includes both a physical and behavioral assessment of the patient. Therefore, the practitioner who conducts this evaluation must be able to complete both a physical and behavioral assessment of the patient in accordance with State law, his or her scope of practice, and hospital policy. Generally, practitioners such as social workers, psychologists and other mental health workers are not qualified to conduct a physical assessment, nor is it in their scope of practice.

Comment: One hospital association questioned why we distinguished restraint and seclusion from other medical interventions initiated when the patient undergoes a sudden change in condition.

Response: Our focus on restraint and seclusion is not to distinguish these interventions from others initiated when a patient suddenly undergoes a change in status; to the contrary, this focus only serves to bring the use of these interventions the same level of attention and concern. As we read through comments, we found that many commenters use restraint or seclusion only when individualized assessment for that particular patient indicates that one or both are necessary as a last resort. However, some seemed to think that restraining a patient was not only acceptable, but a standard, sound, or unavoidable practice. Restraint and seclusion are not standard, benign, or desirable interventions to address a patient's behavior. The use of restraint or seclusion to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others is of the same gravity as other interventions that require the physician's or other attending practitioner's (as noted in the regulation) attention and concern.

Comment: One commenter argued for the onsite presence of the attending physician, since it would introduce someone who did not participate in the incidents leading up to the use of restraint or seclusion who may be more objective in determining whether the intervention is appropriate or whether the restraint or seclusion was imposed as a means of coercion, discipline, retaliation, or convenience.

Response: Including such a requirement would be unnecessarily burdensome. The regulation requires that the attending physician be notified as soon as possible if a restraint or seclusion has not been ordered by the attending physician. The attending physician has a vested interest in determining whether the intervention is appropriate since the physician is ultimately responsible for oversight of the patient's care. If the attending physician believes that the intervention is not needed, he or she may instruct staff to release the patient. If the attending physician wants to speak to the patient or evaluate the patient in person to gather more information, he or she can do so.

Comment: Several commenters suggested that this standard only be applied to those hospitals where deaths or other sentinel events related to restraints or seclusion have occurred.

Response: Once codified, this standard as well as the entire set of existing hospital CoPs are the requirements that all hospitals must meet to participate in the Medicare and Medicaid programs. The CoPs are minimum health and safety standards. They are intended to protect patient health and safety, and to ensure that high quality care is provided to all patients. Although the majority of hospitals are in compliance with the requirements, we cannot develop rules that only apply to some participants or a particular provider group.

Comment: One commenter asked whether any physician who performs the assessment can be any physician, or whether if it must be the patient's attending physician.

Response: As revised in this final rule, standard (e) permits a physician or other LIP, or a trained RN or PA to perform the 1-hour face-to-face evaluation of the patient. We have not specified that the evaluation must be completed by the patient's attending physician. However, if the evaluation is conducted by a trained RN or PA, the attending physician or other LIP responsible for the care of the patient must be consulted as soon as possible. The physician may determine, based on clinical need, how soon he or she should see the patient.

Comment: One hospital stated that it is the facility's responsibility to identify and provide the right number of competent staff to meet the patients' needs. The hospital opposed the one-hour provision as it has adequate, competent staff to assure patient safety and well being.

Response: Based on public comment, we have amended the 1-hour face-to-face evaluation requirement. We agree with the commenter's emphasis on the importance of adequate levels of competent staff.

Comment: One commenter suggested moving away from the requirement for an onsite physician visit, but suggested adding language requiring that, ''If the evaluation is made by telephone, a physician or LIP must personally sign, date, and note the time of the telephone order within 24 hours of the time the order was issued.''

Response: Signature and review of telephone orders arises for other types of orders, not just those involving restraint or seclusion. We see no need to establish separate requirements for how orders for these interventions would be documented.

Comment: One commenter alleged that hospitals are dodging the 1-hour requirement by releasing the patient from restraint or seclusion and starting over with a new order before reaching the 1-hour point.

Response: Ending the intervention prior to the 1-hour point does not mean that the mandated assessment and consultation are no longer necessary. These steps are still required, even if the intervention ends within one hour of initiation.

Comment: Many commenters pointed out that this provision was not in the proposed revision of the hospital CoPs.

Response: Several organizations used this argument as a basis for bringing suit against the Secretary to block implementation of this provision, but the court upheld the validity of the regulation. (See *National Association of Psychiatric Health Systems* v. *Shalala*, 120 F. Supp. 2d 33 (D.D.C. 2000).) As we stated before the court, we believe that this provision is a logical outgrowth

of the December 19, 1997 proposed rule. The court agreed with our position.

Comment: One commenter asked whether the patient has to be released from restraint or seclusion if the physician is unable to arrive within 1 hour.

Response: Since we have revised combined standard (e) to no longer require a physician's onsite visit within 1 hour, this question is no longer pertinent. However, if the face-to-face evaluation is not completed by a physician, other LIP, or a trainer RN or PA, the hospital would be out of compliance.

Comment: Several commenters were concerned that the onsite visit would not be covered by Medicare, since additional visits on the same day cannot be billed for as per the Medicare Claims Processing Internet Only Manual (IOM) pub 100–04, chapter 12, section 30.6.9B.

Response: While multiple visits in the same day by the same practitioner (or another practitioner within the same practice, with the same specialty) cannot be separately billed, practitioners should select a code that reflects all services provided during the date of service (Medicare Claim Processing Internet Only Manual (10m) Pub. 100–04, Chapter 12, section 30.6.9B).

Comment: One commenter asked that both children and adults be monitored by a physician every 15–30 minutes and that documentation be provided.

Response: We do not believe that this high degree of physician involvement is necessarily merited, practical, or reasonable in every case. Based on the patient's status and type of intervention used, more frequent monitoring by a physician, LIP or other trained staff may be necessary. The condition of the patient who is restrained or secluded must be monitored by a physician, other LIP, or trained staffed at an interval determined by hospital policy and based on assessed patient needs.

Comment: Several commenters asked whether CMS will accept a telemedicine evaluation in lieu of face-to-face evaluation.

Response: Since the requirement for face-to-face evaluation has been changed to include a trained RN or PA, there would not necessarily be any need to use telemedicine evaluation unless clinically indicated.

Telemedicine is an important developing field. We are looking at the role of telemedicine in providing healthcare. However, telemedicine is not addressed in this rule. Telemedicine will be addressed at a future date.

Comment: One commenter asked whether an advanced registered nurse practitioner can perform the 1-hour assessment.

Response: In the final rule, combined standard (e) permits an advanced registered nurse practitioner (if recognized by State law and hospital policy as having these abilities within the scope of the individual's license and consistent with individually granted clinical privileges) as being able to order the intervention as well as perform the 1-hour face-to-face evaluation.

Comment: One commenter noted that managed care reimbursement for psychiatric inpatient services is minimal, and the physician will either have to demand that the hospital pay for the physician's time or refuse to extend his or her time ''to unnecessarily observe a patient who has been safely contained by competent mental health professionals.''

Response: This final rule permits the attending physician or other attending practitioner (as noted in the rule) to determine whether and how quickly the physician's presence is merited without arbitrarily requiring it.

16. Limits for Restraint/Seclusion Orders (§ 482.13(f)(3)(ii)(D))

We stated that each written order for a physical restraint or seclusion is limited to 4 hours for adults, 2 hours for children and adolescents ages 9 to 17; or 1-hour for patients under 9. The original order may only be renewed in accordance with these limits for up to a total of 24 hours. After the original order expires, a physician or licensed independent practitioner (if allowed under State law) must see and assess the patient before issuing a new order.

Although a few commenters agreed with the timeframes for length of order specified in the interim final rule with comment period, the majority of comments on this requirement were from advocacy organizations wanting further restriction on the time limits and seeking clarity on who can renew the order. However, one commenter did object to the timeframes for length of order, arguing that they were not based in research and were arbitrary.

Recommendations on this provision varied and included the following:

- Limiting the timeframes for length of order to no more than one-half hour for children, 1-hour for adolescents, and 2 hours for adults.
- Making the timeframes for length of order different for seclusion and restraint use.
- Not using age as the determining criterion since it is an arbitrary factor. Patients present with a variety of clinically important indicators, such as size, weight, gender, history of abuse, disability and medical conditions that should also be used to determine the length of time a patient remains in restraint or seclusion.

Other commenters suggested that each renewal of the order should be accompanied by another face-to-face examination of the patient by the physician. A few commenters were uncertain of who would perform the assessment of the patient prior to renewing the order for the intervention. These commenters asked whether the interim final rule with comment period required physician or LIP face-to-face re-evaluation of the patient before renewal of the order.

Response: We conclude from the nature and number of comments that we did not emphasize our intent for this standard strongly enough. The regulation identifies maximum time limits on the length of each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. The physician or LIP has the discretion to write the order for a shorter length of time. The length-of-order requirement identifies critical points at which there is mandatory contact with a physician or LIP responsible for the care of the patient. In addition, the time limits do not dictate how long a patient is in restraint or seclusion. Staff should be continually assessing and monitoring the patient to ensure that the patient is released from restraint or seclusion at the earliest possible time. Restraint or seclusion may only be employed while the unsafe situation continues. Once the unsafe situation ends, the use of restraint or seclusion should be discontinued. In the final rule, combined standard (e) explicitly states that the intervention must be discontinued at the earliest possible time, regardless of the length of time identified in the order. For example, if a patient's behavior responds to the intervention in 20 minutes, then the restraint or seclusion should be discontinued, even if the order was given for up to 4 hours. If restraint or seclusion is discontinued prior to the expiration of the original order, a new order must be obtained prior to reinitiating the use of restraint or seclusion.

We leave to the physician's or other LIP's discretion whether an onsite assessment prior to renewing the order (for up to 4 hours, 2 hours, or 1 hour, as permitted by the regulation) is necessary. While we agree that prompt physician involvement is important, requiring face-to-face reassessment by a

physician prior to renewal of an order as proposed by the commenters would be overly burdensome. Once the physician or other LIP has assessed the patient's condition, the physician or other LIP chooses a course of action to be followed and directs staff to implement it. We believe that an RN can follow the physician's or other LIP's direction and reassess the patient. Without evidence indicating that a physician's own evaluation versus that of an RN, nurse practitioner, physician's assistant, etc.) somehow better assures patient safety, we cannot accept this suggestion. However, after 24 hours, a face-to-face assessment by a physician or other LIP must occur before a new order is written for restraints or seclusion for the violent or self-destructive patient.

We are unaware of any research or data that suggest that limiting orders to 1 hour is better than limiting them to 4 hours for adults 18 years of age or older, 2 hours for children and adolescents 9 to 17 years of age, or 1 hour for children under 9 years of age. We stress that the timeframes outlined in the regulation are maximums. The ordering practitioner has the discretion to provide an order for a shorter timeframe based on the patient's condition and factors suggested by commenters.

Comment: Some commenters were confused by the term ''renewal'' of an order. We were asked to differentiate between the original order, a renewal order, etc. One commenter stated that under policies in place before the publication of the interim final rule with comment period, continuation of a restraint order beyond the 4-hour time limit was a decision that could be delegated to an RN. The commenter asked whether this rule would require a repeat order from the physician, or whether a 4-hour continuation could be decided upon by other qualified staff, such as an RN. Some commenters supported orders being renewed in this manner for up to 24 hours without a new (physician's) order. One commenter argued that not allowing nurses to evaluate the need to continue the use of restraint or seclusion and, thus, the need to renew an order would create a burden for hospitals.

Response: Each order for restraint or seclusion for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others is limited to the maximum timeframes in the regulation before the physician or other LIP responsible for the care of the patient must be contacted again. At the end of the timeframe, if the continued use of restraint or seclusion is deemed necessary based on a patient assessment, another order is needed. These limited timeframes apply regardless of whether each order is considered a separate, distinct, original order, or whether an order is considered a continuation or renewal of the original order. Because the use of restraint or seclusion is considered an intervention that can only be authorized by the order of a physician or other LIP, it is consistent to require that the determination to continue the intervention meet this standard as well. We believe that it is reasonable to have a trained RN reassess the patient when the original order is about to expire, and then contact the physician or other LIP to obtain direction as to whether the intervention is to be continued and whether other steps are to be taken. The key is the continued medical oversight. There is no prohibition of telephone renewals. We note, however, that at the 24-hour point, if the patient is still in restraint or seclusion for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen and assessed by a physician or other LIP before a new order can be written. In the final rule, we have also specified that each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy.

Comment: One commenter agreed that this provision is clinically sound and warranted. However, the commenter believed that once evaluated, the physician should have the right, based on years of clinical training and supervision and board certification, to continue seclusion or restraint with periodic nursing evaluation for 24 hours.

Response: We believe that the timeframes for length of order, as established by the regulation, are reasonable. We note that the regulatory timeframes do not mandate how long the intervention continues; they only provide check points at which the ordering practitioner, and subsequently the attending physician, must be contacted with updated information regarding the patient.

Comment: One commenter suggested that the timeframes for seclusion should be consistent with professional standards of practice, rather than being regulated by this rule.

Response: We believe the timeframes for seclusion are consistent with professional standards of practice. Seclusion should only be employed while the unsafe situation persists. Once the unsafe situation ends, the use of seclusion should be discontinued. The length-of-order requirements identify intervals at which the ordering practitioner, and subsequently the patient's attending physician, must be informed of the patient's condition so that he or she can make a decision as to how treatment should proceed.

Comment: One commenter suggested that a physician's review of the documentation of the need for restraint [for the management of violent or self-destructive behavior] should be done within 24 hours of the order being issued.

Response: A documentation review alone may not adequately protect the patient. We expect that a physician or other LIP will see the patient if the patient is still restrained or secluded at the 24-hour point. Twenty-four hours of restraint or seclusion for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others is an extreme measure which could potentially seriously harm the patient.

Comment: One commenter believed that allowing 24 hours to elapse before the physician is required to physically see and reassess the patient is too long an interval. If the patient remains extremely agitated after 12 hours in restraint or seclusion, it is evident that the intervention is not successful, and some other intervention is needed. Another commenter argued that if the patient has been restrained or secluded for 4 hours, but preferably 3, a physician consultation is necessary. The medical director needs to be called in to help chart a course of action that will get the patient out of restraint or seclusion if it is proving ineffective.

Response: We agree with the commenter's concern that a patient's continued agitation may indicate a need to consider another course of treatment. However, the reason for the use of restraint or seclusion is to protect the patient or others from harm. The use of these interventions must not end efforts to treat the underlying cause of the behavior; nor is it expected that treatment will come to a complete halt. We expect that the use of restraint or seclusion will only last while the unsafe situation persists. Certainly, trained staff should work with the patient toward release as quickly as possible and use other interventions to de-escalate the crisis behavior.

17. Simultaneous Use of Restraint and Seclusion (§ 482.13(f)(4))

We stated that restraint and seclusion may not be used simultaneously unless

the patient is—(1) continually monitored face-to-face by an assigned staff member; or (2) continually monitored by staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

Comment: One commenter questioned whether our intent is that a patient who has been medicated and placed in seclusion must be continually monitored.

Response: The regulation only requires continual monitoring when restraint and seclusion are used simultaneously. If the use of a drug meets the definition of a restraint, and the patient is simultaneously placed in seclusion, all the requirements related to the simultaneous use of restraint and seclusion apply, including the requirement for continual monitoring.

Comment: One commenter asked for definition of the word ''staff.'' Another commenter asked for more detail regarding the type of monitoring and the level of expertise of the monitors. One commenter argued that children should be monitored by a person who is trained to interact and counsel.

Response: The word ''staff,'' as used in the regulation, has the standard definition found in any dictionary and includes anyone employed by the hospital directly or under a contract. Staff who monitor the patient face-to-face should be trained not only in restraint and seclusion techniques, but also in how to monitor physical and emotional status (taking vital signs, checking physical well-being, working with the patient to help the patient regain self-control, recognizing when the emergency situation has abated and the interventions (either one or both) can be ended). The components of continual monitoring must be determined by staff based on hospital policy, an individualized patient assessment, and the intervention used. Standard (f) specifies the criteria CMS will apply to staff to ascertain whether they have been ''trained''within the meaning of our regulation.

Comment: Some commenters stated that the rule does not explain why restraint and seclusion would be used simultaneously and argued that restraint and seclusion should not be used simultaneously. Some commenters asked to have simultaneous restraint and seclusion banned. These commenters voiced their belief that there is no clinical justification for subjecting a patient to both restraint and seclusion at the same time, other than for convenience of staff, for discipline, coercion, or retaliation. If simultaneous use continues to be permitted, these commenters suggest that patients should be constantly monitored by staff that is in the room or right outside the seclusion room, but in direct visual sight.

Response: Although simultaneous use of restraint and seclusion may be inappropriate in many cases, clinical situations exist where the simultaneous use of restraint and seclusion may legitimately be needed to protect the patient or others from harm. Staff must take extra care to protect the safety of the patient when more restrictive interventions are used. Restraint limits a patient's ability to move or escape from harm. Seclusion of a restrained patient may be necessary to protect a patient from possible abuse, assault or self injury during the intervention. For example, a patient is restrained alone in a room to maintain the patient's privacy. Shielding the patient from contact with others may be more humane and supportive of personal dignity than permitting everyone on the unit to witness what is happening to the patient. In this situation, it may be necessary to lock the door and seclude the patient if a staff member is not assigned to sit with the patient one on one in order to protect the patient.

When the simultaneous use of restraint and seclusion is employed, we would expect to see adequate documentation that justifies the decision for simultaneous use as well as vigilance in continuously monitoring the patient so that the patient's care needs are met. We would expect that the simultaneous use of restraint or seclusion be discontinued at the earliest possible time, regardless of the length of time identified in the order.

We do not agree with the commenters' assertions that these uses necessarily constitute patient abuse. However, there are risks associated with the simultaneous use of restraint and seclusion. Therefore in this final rule, we clarify that all requirements specified under standard (e) apply in the simultaneous use of restraint and seclusion, which is not permitted unless the patient is continually monitored face-to-face by an assigned, trained staff member, or continually monitored by trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient. The hospital is responsible for providing the level of monitoring and frequency of reassessment that will protect the patient's safety.

Comment: One commenter questioned whether the use of a restraint is considered to be seclusion when the restraint prevents the patient from leaving the room. The commenter further queried whether a patient restrained in a seclusion room with the door open and unlocked would be considered to be in seclusion, and whether a patient restrained in the patient's room would be ''in seclusion.''

Response: In a situation where the patient is being restrained by a technique or device that interferes with the patient's mobility, the fact that the patient is confined in a room is a secondary effect. This situation is not equivalent to the use of seclusion. It is important to examine what would happen if the restraint were removed—if the patient would be free to leave the room if the restraint were removed, the patient is not being secluded. Conversely, if the restraint were removed and the door is locked or the staff otherwise physically prevent the patient from leaving the room, then the patient is being secluded.

18. Use of Video and Audio Monitoring

The use of video and audio monitoring met with mixed response. However, overall, the commenters viewed it negatively. Consumer advocates tended to see it as inappropriately depriving the patient of human contact when such contact would be beneficial to help the patient regain self-control, and as not assuring that the patient's physical and psychiatric status are adequately monitored.

Comment: One commenter stated that audio/video monitoring would be ''particularly odious to an individual already trussed up, tied down, and left alone.'' The use of video and audio equipment further alienates a patient who may be craving attention and engaging in the only behavior that will bring about human contact.

Another commenter argued that there is no substitute for face-to-face monitoring with periodic checks of patient's vital signs. The commenter recounted two separate instances where patients died while in restraints and seclusion. In both instances, the paramedics were unable to ventilate the patients because they were unable to place a tube down the throat of the patient. The onset of rigor mortis demonstrated that these patients had been dead for several hours before hospital staff discovered them and called the paramedics. The nursing logs for both patients indicated that the patients had been checked every 15 minutes. In these instances, ''checked'' meant looked at through a window into the seclusion room.

Some commenters argued that audio and video monitoring is costly and would result in financial burden to the hospitals. One commenter explained

that his hospital does not have the financial resources to hire additional nurses or nurse aides to perform one-to-one monitoring, nor does it have the resources to buy video systems for monitoring. Another commenter characterized electronic monitoring as costly and invasive of privacy.

A commenter argued that face-to-face monitoring only increases patient agitation and that both face-to-face and video/audio monitoring confirm the misperceptions of psychotic patients who are paranoid or delusional.

Other commenters did not object to alternative methods for monitoring, but had suggestions about requiring both. One commenter asked that we permit audio monitoring, but not require it. Another commenter suggested that we reconsider the need for audio monitoring if video monitoring is in place.

One commenter believed that video monitoring and taping was appropriate to ensure proper patient monitoring and quality control; however, this commenter believed that the regulations should also require staff to be in the patient's room. One commenter recommended ongoing audio/video monitoring to protect patient safety.

Another commenter asked for a more prescriptive definition of ''close proximity.'' The commenter understood that the intent of requiring staff to be in close proximity is to assure that hospital staff could quickly reach a patient should a safety issue arise.

Response: We agree that audio and video monitoring are not substitutes for the therapeutic intervention that should be occurring to help the patient regain self-control or for the level of monitoring necessary to assure that the patient is safe and that the patient's care needs are met. The use of video and audio monitoring equipment does not eliminate the need for other therapeutic interventions or frequent assessment of the patient's needs and status. For one patient, continual monitoring face-to-face by an assigned staff member may be appropriate and necessary. For another patient, the continual presence of an assigned staff member may cause the patient to become more agitated. In this situation, continual monitoring by trained staff using both video and audio equipment with periodic in-room monitoring may be more appropriate. In either situation, vigilant monitoring is necessary to protect the patient from harm, and ensure that the intervention is discontinued at the earliest possible time.

The hospital is responsible for providing the level of monitoring and frequency of reassessment that will protect the patient's safety. Continual monitoring cannot happen solely from outside the seclusion room. Staff must enter the seclusion room in order to—(1) monitor a patient's vital signs, circulation, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, etc., and assess and re-evaluate the patient; (2) provide for nutritional needs; range of motion, and elimination needs; and (3) provide other necessary therapeutic interventions and patient care. In response to comments, we have therefore revised combined standard (e) to clarify that all requirements specified under standard (e) apply in the simultaneous use of restraint and seclusion.

In response to comments that requested that we reconsider requiring both video and audio monitoring, we believe that neither video nor audio monitoring alone adequately protect patient safety when restraint and seclusion are used simultaneously. We do not require video and audio monitoring; instead, it is one method the facility can use to monitor its patients.

In response to the request for a more prescriptive definition of ''close proximity,'' the intent is to ensure that staff is immediately available to intervene and render appropriate interventions to meet the patient's needs. However, based on the number of possible unit configurations, we believe an outcome-oriented requirement is more appropriate than a more prescriptive one.

Comment: One commenter suggested that the regulations should specify that under no circumstances should a restrained patient be left unattended, as a patient in restraint is vulnerable to attack or mistreatment from others.

Response: Including such a requirement would be unnecessarily burdensome. As discussed earlier, we agree that a patient is more vulnerable to possible abuse, assault, or self injury during a more restrictive intervention. We expect staff to take extra care to protect the safety of the patient when more restrictive interventions are used. Regardless of the intervention used, the hospital is responsible for providing the level of monitoring and frequency of assessment necessary to protect the patient's safety. We believe hospitals should have the flexibility to provide the level of monitoring and frequency of assessment necessary to protect the patient's safety based on hospital policy and an individualized patient assessment.

Comment: Due to nationwide staff shortages, one commenter stated that his facility would be unable to meet the requirement.

Response: As one commenter offered earlier, it is the hospital's responsibility to assure that it has adequate staff available to meet the patients' needs. Given the acuity of a patient in restraint and seclusion simultaneously, we believe that heightened monitoring and intervention are merited.

Comment: One commenter stated that the requirement for face-to-face monitoring places staff at higher risk for injury.

Response: We believe that the required training elements within this regulation will promote staff awareness and expertise in handling potentially hazardous situations.

Comment: One commenter suggested that a better approach for increasing physician oversight and involvement would be to require a log of restraint use to be kept by the hospital, along with quarterly reports generated for local peer review organizations to track restraint and seclusion use. Patterns of excessive use would emerge more readily than they would otherwise under the current requirements.

Several commenters suggested requiring a restraint/seclusion log, and included elements that should be part of this log, such as the time initiated, discontinued, time physician was contacted, documentation of physical exams, etc. Additionally, other commenters believed that quality improvement efforts could more appropriately address the concerns regarding patient safety and quality of care.

Response: We agree. Although not mandated in this rule, we expect a hospital will address, as part of its quality assessment and performance improvement (QAPI) program, patient safety and quality of care issues. We also believe that this sort of tracking and monitoring may be appropriate as part of a hospital's QAPI program. However, including such a requirement would be unnecessarily burdensome. Hospitals should have the flexibility to identify and monitor the quality indicators that are most critical to the patient population(s) that they serve.

Comment: One commenter questioned how face-to-face monitoring should be documented.

Response: The regulation does not specify how face-to-face monitoring will be documented. This should be addressed by hospital policy.

19. Reporting of Death(s) Related to Restraint/Seclusion (§ 482.13(f)(7))

We stated that the hospital must report to CMS any death that occurs

while a patient is restrained or in seclusion, or where it is reasonable to assume that a patient's death is a result of restraint or seclusion.

Comment: Several commenters noted that all deaths are routinely reported to State authorities.

Response: As noted earlier in this preamble, while there may be local mechanisms for reporting deaths, there is, at present, no nationwide system for reporting these deaths. We have estimated that the total number of deaths related to the use of restraint and seclusion in hospitals will be less than 10 per year. Therefore, given that the average number of reports per hospital is one or less, we do not believe that it is burdensome to ask that the hospital notify the CMS regional office if a patient dies while in restraint or seclusion, or where it is reasonable to assume that restraint or seclusion contributed directly or indirectly to the patient's death.

Comment: One commenter who supported the provision as written opposed requiring more detailed reporting and expressed concern about routine reporting to the Protection and Advocacy organizations (P&As). (Providing the P&As with information was mentioned in the preamble of the interim final rule with comment period.) Some commenters echoed this concern, expressing serious reservations about CMS's ability to maintain the confidentiality of the sensitive information provided in accordance with the new rule. These commenters did not believe that information provided to the P&As would be protected from disclosure or legal discovery. One commenter asked whether CMS would maintain the confidentiality of the information, or share it with outside entities.

Those commenters who opposed sharing the information with other entities argued that forcing hospitals to report injuries and the circumstances around them would in many cases require release of information that hospitals gather through their own peer review activities. Almost all 50 States protect information gathered in peer review and other quality internal improvement processes from discovery by lawyers. One commenter referred to *Bredice* v. *Doctor's Hospital, Inc.* (50 FRD 249 (D.D.C. 1970)), citing it as a case in which the court found that it was in the overwhelming public interest to maintain the confidentiality of the minutes and reports of medical staff meetings during which doctors critically analyze the hospital's medical care. The commenter argued that self-critical analysis privilege is now judicially recognized as a result of this case.

In contrast, a core of commenters from the public and the patient advocacy community supported sharing this information with the P&As, stressing the importance of partnering between CMS and P&As. These commenters encouraged a mandatory, detailed system of reporting to the P&As to ensure comprehensive investigations of incidents where patients die or are injured during restraint or seclusion use.

Response: Since the publication of the interim final rule with comment period, we have implemented a process for restraint or seclusion death reporting. We centrally track reports of death from restraints or seclusion occurring in hospitals. We use this information to: Authorize onsite investigations and complaint surveys of these hospitals, in accordance with the current complaint investigation process; and to inform the Federally-mandated P&A entity in the respective State or territory. P&A programs are congressionally authorized (in accordance with 42 U.S.C. 10801 et seq.) to access facilities and to investigate abuse and neglect complaints.

Comment: One commenter asked what information must be provided by the hospital and the timeframe within which the hospital must report the information to CMS. Some commenters proposed introducing timeframes for reporting, such as contacting the CMS regional office within 4 days of a patient death and the P&A within an additional 3 days. The commenters who supported such timeframes cited proposed national legislation, The Children's Health Act of 2000 (the CHA). The commenters who asked for definite timeframes stated that delays in reporting compromise the ability to investigate effectively (staff may leave, medical/documentary evidence may be lost or concealed, and potentially deadly practices continue). Other commenters suggested that CMS require reporting to the P&A within 24 hours of an incident.

Response: The CHA was signed into law on October 17, 2000 (Pub. L. 106–310). Section 592 of the CHA establishes minimum death reporting requirements. This final rule conforms to these requirements. We have revised our requirements to specify that the hospital report each death to the CMS regional office by telephone no later than the close of business the next business day following knowledge of the patient's death. This information will be relayed to CMS central office and the State survey agency, inasmuch as it acts as a direct agent of CMS. Our central office maintains a database to compile information related to deaths associated with seclusion or restraint.

Comment: Some commenters suggested that the regulation excuses hospitals from revealing many deaths precipitated by the misuse of restraint or seclusion by allowing the hospital to make the determination of whether a patient's death is reasonably assumed to have resulted from restraint or seclusion. These commenters strongly believed that providers tend to dismiss restraint-related deaths as ''unfortunate isolated incidents,'' not the manifestation of individual abuse or systemic failures, and that hospitals can rationalize that deaths were due to a patient's underlying condition or ''natural causes.'' Several commenters cited an example of the death of a young man who suffered a severe asthma attack soon after fighting with another patient and being restrained. According to the commenters, the death was ruled to be due to natural causes, even though the medical examiner found that the stress of the fight and restraint triggered the attack. Some commenters indicated that a complicating issue is that death may occur after a patient has been restrained or secluded in an originating facility, and is then transferred to another facility. The receiving facility may be unaware of what has transpired at the originating facility and may not report the death.

To address this issue, these commenters suggested that at a minimum, CMS specify that any deaths that occur within one week of restraint or seclusion use be assumed to be the result of restraint or seclusion. Optimally, however, these commenters argued for reporting all deaths of patients with a psychiatric diagnosis or mental retardation. The commenters stated that in this way, CMS could remove the subjectivity currently permitted by allowing the hospital to make a determination that the death is ''reasonably assumed'' to be a result of restraint or seclusion use.

These commenters also stated that a requirement for reporting the deaths of all patients with a mental retardation or psychiatric diagnosis would also permit CMS and the P&As to capture deaths that occurred post-transfer, as a result of restraint and seclusion practices at another facility.

Response: We have revised the reporting requirements. The hospital must report to CMS each death that occurs while a patient is in restraint or in seclusion or both at the hospital; and, each death known to the hospital that occurs within 1 week after restraint

(whether physical restraint or drugs used as a restraint) or seclusion, in cases in which it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. We have also clarified the meaning of ''reasonable to assume.'' As a result, ''reasonable to assume'' includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or deaths related to chest compression, restriction of breathing, or asphyxiation. In addition, we have moved the reporting requirements from standard (f) and created a separate standard (standard (g)) that addresses these requirements. This was done to clarify that all deaths associated with the use of seclusion or restraint or both must be reported. The reporting requirements in standard (g) are applicable to restraint and seclusion use.

We are not adopting the commenter's suggestion that all deaths of patients with a psychiatric or mental retardation diagnosis be reported to CMS; nor will we assume that all deaths that occur within 1 week of the use of restraint or seclusion are the result of restraint or seclusion.

Comment: A commenter stated that the reporting process is severely deficient because inadequate information would be provided to CMS and the P&As. The commenter suggested specific elements that should be reported, including—

- Identity of deceased/injured patient;
- Patient's age;
- Identity of patient's guardian, if applicable;
- Identification of next of kin, in cases involving patient death;
- Date of death/injury;
- Patient's home address;
- Medications patient was taking/other medical services provided;
- Cause and circumstances of death/injury;
- Whether/by whom death/injury is being investigated; and
- Identity of person making report.

Some commenters believed that the report submitted to CMS should be standardized and in writing.

Response: We agree that the suggested elements should be reported. However, to allow some flexibility for hospitals, we are not specifying these elements in the regulation text. In the final rule, standard (g), we have specified that each death referenced in this section must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death. In addition, we have added a requirement that staff must document in the patient's medical record the date and time the death was reported to CMS.

Comment: One commenter suggested replacing the word ''assume'' with ''suspicion or belief.''

Response: We have retained use of the word ''assume'' and added language to clarify the meaning of ''reasonable to assume.''

Comment: One commenter indicated that the accrediting organization should also receive this information as deaths would be ''sentinel events'' under JCAHO policy.

Response: We currently inform the hospital's accrediting organization when we receive a death report from a hospital. In addition, hospitals should report deaths to their accrediting organization in accordance with their accreditation standards. JCAHO instituted a sentinel events reporting policy (effective October 31, 1998) that encourages hospitals to voluntarily report such occurrences within 7 days of the incident.

Comment: One commenter opposed the reporting requirement, stating that there is no need to increase the number of people involved with the monitoring and/or investigating patient deaths. Another commenter echoed this sentiment, noting that this requirement is duplicative of JCAHO's sentinel event reporting requirement, and that we should simply share data with the JCAHO instead.

In contrast, a private psychiatric health system agreed with this provision, saying it makes good sense. Many commenters supported this provision, although they suggested measures that they believed would strengthen it, such as requiring that serious injuries be reported and specifying lists of elements to be provided to CMS.

Response: Section 592 of the CHA mandates death reporting and this final rule incorporates/addresses these requirements. These requirements address gaps in existing reporting systems that inhibit the ability to conduct meaningful analysis of trends and target problems. JCAHO's system is voluntary, not mandatory, and 20 percent of the hospitals that participate in Medicare and Medicaid are not JCAHO accredited. To adequately track deaths, mandatory reporting is needed by all hospitals.

We believe that injury reporting is beyond the scope of the CHA; and therefore, we are not incorporating injury reporting provisions in this final rule. However, we would expect that serious injuries related to the use of restraint or seclusion would be monitored through the hospital's QAPI program.

Comment: Several commenters suggested that reporting should include not only deaths of patients, but injuries to staff during the restraint or seclusion procedure.

Response: We do not require reporting of staff injuries associated with the use of seclusion or restraint. However, hospitals may establish their own systems for tracking such information.

Comment: One commenter suggested requiring hospitals to report the number of seclusion or restraint occurrences; the total number of patients secluded or restrained; the average number of hours per occurrence; and, the average number of hours in seclusion or restraint per patient. The commenter also recommended that we protect patient privacy by withholding of identifying information but otherwise reporting demographic data.

Response: We believe that the burden of such an approach would have the opposite effect; that is, it would most likely result in hospital under-reporting of patients in restraint or seclusion. However, although not mandated in this rule, we expect that a hospital will address utilization of restraint and seclusion as part of their QAPI program. Regarding the recommendation to this information is withheld identifying information, required to investigate or otherwise follow-up on a reported death, if necessary.

Comment: Some commenters believed that serious injuries, both physical and psychological, must be reported to be proactive and to prevent deaths. These commenters realized that there may be some additional burden on hospitals, but believed that burden could be minimized by limiting reports to more severe types of injuries. One commenter asked that if we do add injury reporting, that it be limited to injuries that require medical attention.

Some commenters offered a general argument that the P&As would be a better entity than CMS to receive the information and investigate the incidents. For example, commenters stated that the P&As have trained investigators who are already a part of the Department of Health and Human Services. Commenters also stated that the P&As need to be involved to adequately perform the necessary investigations.

In contrast, several commenters questioned why the P&As should be provided this information, since they have no authority to sanction a hospital and are not able to act as CMS's agent. The commenters stated that this

provision would expose the provider to two possible investigations without any clear and convincing rationale.

Response: We are not adding any injury reporting requirement in this rule. Aside from the issue of hospital burden and potential disagreement on what constitutes a reportable event, a fundamental problem in requiring injury reporting for this setting is the administrative burden on the program itself. Many commenters seemed to acknowledge this limitation, in that they used it as an argument for the need for increased P&A involvement. So, these commenters may argue, even if CMS cannot administratively handle injury reporting, this information could be routed to the P&As for investigation or made available to the public.

We believe that this points to a misperception of the roles of the various agencies. A P&A cannot act as our agent. There is no statutory connection between CMS and the P&As, as there is between CMS and the State survey agencies. The P&A cannot take an enforcement action on our behalf. While we support the role of the P&As, and we believe that a coordinated effort between agencies is appropriate, we also believe that the roles should not blur into each other. We have a distinct interest in the health and safety of patients, which is shared by the P&As. However, we also have a statutorily-governed relationship with the providers of services. That relationship is built on the expectation of confidentiality. We need information from the hospitals inasmuch as we evaluate whether they are meeting the standards for care we have set.

Comment: Mental health advocacy groups and P&A organizations requested that the name, address, phone number, and brief description of services provided by the P&A be required to be posted in each hospital.

Response: We believe requiring that this information be posted would be unnecessarily burdensome. Hospitals are already required to provide patients with contact information if the patient wishes to file a grievance.

Comment: One commenter stated that if serious injury or death occurs, that event needs to be recorded and an independent auditor needs to investigate the incident. The auditor should be clinically oriented, not of an administrative background.

Response: We only require that deaths be reported. Upon receipt of the information, we can initiate an independent investigation of the death. We are not requiring that hospitals report serious injuries, but this type of information could be reviewed while surveyors are onsite. In addition, we will not require that the hospital hire an independent auditor to investigate deaths and serious injuries.

Comment: One commenter charged that the reporting requirement is not consistent with initiatives to create a government that works better and costs less.

Response: We disagree. We do not believe that the revised reporting requirements are overly burdensome. Furthermore, the reporting system serves as an outcome indicator that can be used to target our investigational efforts.

Comment: One P&A supported the reporting of serious injuries, but argued for added resources for P&As so that meaningful and prompt investigations can occur.

Response: We agree with the importance of P&A investigations. However, we do not allocate funding for the P&A programs.

Comment: One commenter indicated that it is burdensome for a hospital to have to review charts on all patient deaths to determine if restraints or seclusion were used with the patient. The commenter questioned whether only Medicare and Medicaid beneficiary deaths need to be reported, or if all patient deaths related to restraint or seclusion must be reported.

Response: The CoPs apply to all patients in a Medicare- and Medicaid-participating hospital, not just Medicare/Medicaid beneficiaries. Therefore, all patient deaths associated with the use of restraint or seclusion or both must be reported. We do not view this as particularly burdensome since these deaths should be infrequent.

Comment: A commenter stated that the regulation does not discuss a penalty for failure to report.

Response: Noncompliance with this requirement, as with any of the others in these standards, constitutes a violation of the CoPs that would potentially be subject to termination of the hospital provider agreement as described at 42 CFR 489.53.

IV. Provisions of the Final Rule

For reasons specified in section III of the preamble to this final rule, we are codifying the Patients' Rights CoP within the current hospital CoPs under Subpart B—Administration at § 482.13. The eight standards specified in this final rule establish minimum protections and rights for patients. Any changes that have been made to clarify or strengthen the provisions that appeared in the interim final rule with comment period are noted in the following description of the provisions.

The first standard, ''Notice of Rights,'' requires the patient or the patient's representative, as permitted by State law, to be informed of the patient's rights prior to furnishing or discontinuing care whenever possible. The standard also requires that the hospital have a grievance process, that the patient be informed of whom to contact to file a grievance, and that the process include specific elements. This standard has not been revised; and therefore, is being finalized without change.

The second standard, ''Exercise of Rights,'' provides the patient the right to participate in the development and implementation of his or her plan of care, and to request or refuse treatment. This standard supports the patient's right to make decisions regarding his or her care and to formulate advance directives and have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with § 489.102 (Requirements for providers). This standard also supports the patient's right to have a family member or representative of his or her choice and his or her physician notified promptly of the patient's admission to the hospital. This standard has not been revised; and therefore is being finalized without change.

The third standard, ''Privacy and Safety,'' which includes the right to personal privacy, to receive care in a safe setting, and to be free from all forms of abuse or harassment. This standard has not been revised; and therefore is being finalized without change.

The fourth standard, ''Confidentiality of Patient Records,'' provides the patient's right to the confidentiality of his or her records, and to access those records. This standard has not been revised; and therefore is being finalized without change.

The fifth standard, ''Restraint or seclusion,'' differs both in content and in application from the standard presented in the interim final rule with comment period. We have revised and combined the requirements contained in standards (e) and (f) in the interim final rule into a single, combined standard in the final rule. The final, combined standard (e) applies to the use of restraint, the use of seclusion, as well as the simultaneous use of restraint and seclusion regardless of patient location.

The revised, combined standard (e) states that all patients have the right to be free from physical or mental abuse, and corporal punishment. It retains the patient's right to be free from restraint or seclusion, of any form, imposed by staff as a means of coercion, discipline,

convenience, or retaliation. It also states that restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, staff or others and must be discontinued at the earliest possible time.

A significant change from the interim final rule with comment period to this final rule is that standard (e) provides a revised definition of ''restraint.'' In the final rule, we adopted the restraint definition contained in the CHA. A restraint is any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. The final rule also clarifies that a restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). The seclusion definition contained in the interim final rule with comment period has been retained with minor content revisions. Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Standard (e) also clarifies that seclusion may only be used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others.

All of the requirements contained in the current standard (e) ''Restraint for acute medical and surgical care'' are also contained in the current standard (f) ''Seclusion and restraint for behavior management.'' These requirements have been moved to the combined standard (e) in the final rule. The more stringent requirements contained in the current standard (f), but not in the current standard (e) have also been moved to the combined standard (e) in the final rule. These more stringent requirements are: Time limits on the length of each order, and the 1-hour face-to-face evaluation. The final rule clarifies that these two requirements only apply when restraint or seclusion are used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. Requirements for the simultaneous use of restraint and seclusion have also been retained in the final rule.

Standard (e) retains the following requirements: Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient or others from harm; the type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient or others from harm; and, the use of restraint or seclusion must be in accordance with a written modification to the patient's plan of care, and implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.

Standard (e) retains and clarifies the requirement that use of a restraint or seclusion must be in accordance with the order of a physician or other LIP who is responsible for the care of the patient as specified under § 482.12(c) and is authorized to order restraint or seclusion by hospital policy in accordance with State law. The standard also requires that the restraint or seclusion order never be written as a standing order or on an as needed basis (PRN), and that the attending physician must be consulted as soon as possible if restraint or seclusion is not ordered by the patient's attending physician. Standard (e) also sets limits on the length of each order for restraint or seclusion used to manage violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others based on the age of the patient, and states that the order may only be renewed in accordance with these limits for up to a total of 24 hours unless superseded by State law that is more restrictive. After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, a physician or other LIP (if allowed by State law) must see and assess the patient. Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy. Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

Further, standard (e) specifies that the condition of the patient who is restrained or secluded must be monitored by a physician, other LIP or by trained staff at an interval determined by hospital policy. The criteria for staff to be considered ''trained'' are specified under § 482.13(f). In addition, physician and other LIP training requirements must be specified in hospital policy. At a minimum, physicians and other LIPs authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion.

A significant change from the interim final rule with comment period to this final rule is that standard (e) has been revised to expand the type of practitioners permitted to conduct the 1-hour face-to-face evaluation. When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, a physician or other LIP, or a RN or PA trained in accordance with the requirements specified under § 482.13(f), must see the patient face-to-face within 1-hour after the initiation of the intervention. This practitioner must evaluate the patient's immediate situation, the patient's reaction to the intervention, the patient's medical and behavioral condition, and the need to continue or terminate the restraint or seclusion. As specified at § 482.13(e)(13), State law (by statute or regulation) regarding the 1-hour face-to-face evaluation may be more restrictive than these requirements. If the 1-hour face-to-face evaluation is conducted by a trained RN or PA, the attending physician or other LIP who is responsible for the care of the patient as specified under § 482.12(c) must be consulted as soon as possible after completion of the evaluation.

Standard (e) clarifies requirements related to the simultaneous use of restraint and seclusion. All requirements specified under standard (e) apply in the simultaneous use of restraint and seclusion, which is not permitted unless the patient is continually monitored face-to-face by an assigned, trained staff member, or continually monitored by trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

Finally, standard (e) has been amended to specify elements of documentation. When restraint or seclusion is used, there must be documentation in the patient's medical record of the following: The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior that jeopardizes the

immediate physical safety of the patient, a staff member, or others; alternatives or other less restrictive interventions attempted (as applicable); the patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and, the patient's response to the intervention(s) used, including the rationale for continued use of the intervention. When restraint or seclusion is used for violent or self-destructive behavior, documentation must also include findings from the 1-hour face-to-face assessment.

Standard (f) is a new standard that addresses staff training requirements. A patient has a right to the safe implementation of restraint or seclusion by trained staff. Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion before performing any of these actions, as part of orientation, and subsequently on a periodic basis consistent with hospital policy.

In addition, standard (f) states that the hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

- Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require restraint or seclusion;
- The use of non-physical intervention skills;
- Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition;
- The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);
- Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary;
- Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation; and,
- The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors. The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.

Standard (g) is a new standard that addresses reporting requirements for deaths associated with the use of restraint or seclusion. The hospital must report to CMS each death that: occurs while a patient is in restraint or in seclusion at the hospital; occurs within 24 hours after the patient has been removed from restraint or seclusion; and, each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. For the purposes of this regulation, ''reasonable to assume'' includes, but is not limited to deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation. Each death referenced in this section must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death. Staff must document in the patient's medical record the date and time the death was reported to CMS. Although we have modified some of the provisions to address public comments, these modifications do not lessen protections afforded patients who are restrained or secluded.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-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 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.

Section 482.13 of this document contains information collection requirements; however, these information collection requirements are currently approved under OMB control number 0938–0328, ''Hospital Conditions of Participation'' with a current expiration date of January 31, 2008.

This document makes changes to the requirements in the following paragraphs within § 482.13 that contain information collection requirements. In this final rule, we have combined the requirements that were set forth in the interim final rule under standard § 482.13(e) Standard: Restraint or Seclusion used in the provision of acute medical, pre and post surgical care and § 482.13(f) Standard: Seclusion and restraint for management of violent, self destructive or aggressive behavior into a single standard, § 482.13(e) Standard: Restraint and seclusion. This change is designed to address restraint and seclusion use regardless of the treatment setting in which it occurs.

Section 482.13(e) Standard: Restraint or Seclusion

Although we believe many hospitals are already complying with the requirements in this standard through usual and customary practices, the revisions, reformatting, and additions to the existing regulatory text may result in increased burden. However, we believe this increased burden should be offset by reduced burden upon the physicians and LIPs since the need to assess the patient within 1-hour of the initiation of restraint or seclusion can be performed by other qualified LIPS as well.

Section 482.13(f) Standard: Restraint or Seclusion: Staff Training Requirements

As we have discussed in greater detail in sections III. and IV. of the preamble to this final rule, revisions have been made to the proposed § 482.13(e). Paragraph (e)(15) has been added to address the documentation requirements when restraint and seclusion are used simultaneously. We believe the majority of hospitals already maintain such documentation. Therefore, the burden associated with this requirement will not impose undue hardship on most hospitals. We believe that compliance with these standards constitutes a usual and customary business practice and the burden associated with the requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2).

Section 482.13(g) Standard: Death Reporting Requirements

The requirements contained in this section were previously contained in paragraph (f)(7) of this section and are currently approved under OMB control number 0938–0328. See section VI. of the preamble to this final rule for a summary of the estimated burden hours associated with this section.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following: Centers for Medicare and Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development Group, Room C4–26–05, 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: Carolyn Lovett, CMS Desk Officer. Fax (202) 395–6974.

VI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act (the Act), the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This final rule revises the restraints and seclusion provisions of the Patients' Rights CoP that were published in the July 2, 1999 interim final rule with comment period. The CoPs are the basic health and safety requirements that a hospital must meet in order to participate in the Medicare program. This rule will implement regulations that are intended to reduce the use of restraint and seclusion, eliminate the potential for adverse outcomes when restraint, seclusion or both are implemented, and minimize the burden associated with compliance with the rule. While it is not possible at this point to determine definitively the additional costs to the Medicare program resulting from this rule, we estimate that the impact will be below $100 million; and therefore, we have determined that this final rule is not a major rule.

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 jurisdictions. Individuals and States are not included in the definition of small entity. We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural facilities. In addition, 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 since superseded by ''core based statistical areas'' and has fewer than 100 beds.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $120 million. This rule has no impact on the expenditures of State, local, or tribal governments, and the impact on the private sector is estimated to be less than $120 million.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Thus rule will not have any effect on State and local governments.

In the December 19, 1997 **Federal Register**, we issued a proposed rule that detailed our plans to revise all of the hospital CoPs which emphasized lessening Federal regulation to eliminate unnecessary structural and process requirements, focus on outcomes of care, allow greater flexibility to hospitals and practitioners to meet quality standards, and place a stronger emphasis on quality assessment and performance improvement. The proposed rule indicated our intent to include a new Patients' Rights CoP for hospitals that contained rights not addressed in the then current CoPs. We solicited comments on the Patients' Rights CoP and received strong support for its establishment from the public, mental health advocacy groups, media, and the Congress. These groups and individuals expressed serious concern about improper care of patients in the hospital setting, particularly with regard to the use of seclusion and restraint.

On July 2, 1999, we issued an interim final rule with comment period that set forth requirements supporting and protecting patients' rights in the hospital setting. It included four standards that were finalized to ensure minimum protections of each patient's physical and emotional health and safety. These standards address each patient's right to: Notification of his or her rights; the exercise of his or her rights in regard to his or her care; privacy and safety; and confidentiality of patient's records.

Additionally, this interim final rule specifically addressed the right to be free from the use of seclusion and restraint and included various requirements to protect the patient when use of these interventions is necessary.

B. Anticipated Effects

1. Effects on Providers

We anticipate the impact of these finalized standards will vary widely among hospitals. However, we do not have the benefit of several key pieces of information. For example, we do not have reliable data on the prevalence of restraint and seclusion use, data on the volume of staff in hospitals, or data on the varying levels and qualifications of hospital staff who may be involved in restraint and seclusion use. Given these and a variety of other factors, it would be unfair to calculate an estimate based on the average of the limited available data. In another example, with respect to training, this rule will have significantly less impact on a hospital that already has a proactive training program in place and has significantly reduced its restraint and seclusion use than it will in a hospital that has not independently taken such an approach.

Factors such as size, services rendered, staffing, and patient populations vary as well. An additional consideration was noted when one caller who telephoned for clarification on the provisions of the interim final rule with comment period complained that some hospitals specifically screen out patients with potentially violent,

self-destructive behavior, so that this population is diverted to State systems, in turn, resulting in these State systems potentially bearing the brunt of this burden. We are hesitant to make impact estimates in this final rule that may not account for these and other unforeseen variations. Thus, we reserve the right to provide estimates when feasible. Below we discuss the anticipated effects on providers of the standards related to restraints and seclusion.

a. Section 482.13(e) Standard: Restraint or Seclusion

Standard 482.13(e), previously entitled ''Restraint for acute medical and surgical care'' in the interim final rule with comment period, is now entitled ''Restraint or seclusion'' in this final rule. The existing regulation sets out the patient's rights in the event he or she is restrained or secluded, and limits when and by whom restraint or seclusion can be implemented. We have combined the existing standards 482.13(e) and 482.13(f) for clarity since it is our goal to have the use of restraint or seclusion reduced in all settings of the hospital. The revisions, reformatting, and additions to the existing regulatory language will not result in additional impact upon hospitals associated with their efforts to comply with this regulation. Instead, since we have provided more clarity in the definition of a restraint with respect to medical and surgical services, burdens on hospitals should decrease.

In previous § 482.13(e)(3)(B), we stated the patient's ''treating'' physician be consulted in the event of restraint or seclusion. However, based on comments we have revised the requirement at § 482.13(e)(7) to reflect the need to consult the ''attending'' physician instead of the ''treating'' physician as soon as possible if the attending physician did not order the restraint or seclusion.

We have revised and expanded § 482.13(e)(4) to specify, at § 482.13(e)(10), that a physician, other licensed independent practitioner or trained staff meet the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy. We also recognize there will be some impact associated with performing patient assessment and monitoring. However, we view patient assessment and monitoring as a standard component of patient care.

Section 482.13(f)(3)(ii)(c), now § 482.13(e)(7), clarifies that the ''attending'' physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion. Although this may minimally increase burden to hospitals, we believe it is a best practice for patient safety.

We have added elements at § 482.13(e)(15) that monitoring must occur face-to-face by trained staff or by using both video and audio equipment, when there is simultaneous use of restraint and seclusion. We have added elements at § 482.13(e)(16) regarding the documentation that must be included in the patient's medical record when the patient is restrained or secluded, including the 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior, the patient's behavior and intervention used, alternatives or other less restrictive interventions attempted (as applicable), the patient's condition or symptom(s) that warranted restraint or seclusion use, and the patient's response to the use of the restraint or seclusion intervention, including the need for continued use of restraint or seclusion. We do not believe additional burdens are imposed by this requirement since it is a routine and customary practice to document the circumstances surrounding such an event for comprehensiveness of patient care.

In the interim final rule with comment period at § 482.13(f)(3)(ii)(c), we required that the physician or other LIP must see and evaluate the patient's need for restraint or seclusion within 1-hour after the initiation of restraint or seclusion. This 1-hour on-site physician or LIP evaluation was the most controversial provision of the interim final rule with comment period.

Limited data has been gathered in the industry to date regarding the prevalence of restraint and seclusion use. However, among the limited data that is available, it reflects the use of restraint or seclusion for behavior management only per the current requirement at 482.13(f).

For example, based on information provided to us by the National Association of Psychiatric Health Systems (NAPHS), fifty NAPHS members supplied data for the cost of complying with the CMS requirements that a physician or LIP evaluate a patient face-to-face within 1 hour of the initiation of restraint or seclusion. The data that was supplied combined: (1) The cost of maintaining a physician or LIP on call to be available in case there is an event of a restraint or seclusion and (2) the cost of having a physician or LIP come to the facility to evaluate a patient within 1 hour when a restraint or seclusion episode occurs. The average cost was $80,789 per facility per year.

The NAPHS further discussed that there are approximately 250 freestanding specialty hospitals in the United States. This number does not include the approximately 1,400 behavioral health units of general hospitals or government (state and county) psychiatric specialty hospitals. The 1 hour rule applies to all these facilities.

An average NAPHS member hospital is a 60–80 bed community-based specialty hospital. The NAPHS stated the average total budget of such facilities is approximately $10-$15 million hence the NAPHS views this $80,000 to be a very significant portion of its operating budget.

We heard from many hospitals that this requirement was impossible to fulfill because of the lack of available personnel, geographic challenges, and the high costs associated with maintaining this degree of coverage. This was particularly noted among rural hospitals. Furthermore, these commenters stated that a required onsite visit is costly with no demonstrable benefit in many cases.

We determined that the heightened degree of intervention and restriction of who can perform this assessment was excessive and would not be feasible in many rural or remote areas. In response to industry concerns, we have expanded who may perform the 1-hour face-to-face evaluation. Conversely, some commenters requested on-site mandatory physician presence within half an hour of initiation of restraint or seclusion. Again, we believe this would be too burdensome for hospitals in rural or remote areas to comply.

Thus, we anticipate the expansion of who may perform the 1-hour face-to-face evaluation will be less burdensome to hospitals. We believe the training required by this rule will equip staff with appropriate skills for handling escalating or aggressive patient behavior and should reduce overall use of restraints. However, we are aware that the facility's size, progress in reducing the use of restraint or seclusion, and other characteristics will have a varying impact upon each facility's performance of this requirement.

Again, the NAPHS stated their respondents reported it took an estimated 30 minutes to 1 hour to document all the specific elements required by CMS after a restraint or seclusion episode. This included several elements unique to the rule such as notifying the attending physician if the restraint was ordered by someone other than the patient's attending physician.

Thus, our burden estimate is based on a median timeframe (that is, 45 minutes) that we believe it takes to complete the required documentation in the patient's medical record. However, since we are unable to estimate the prevalence of restraint and seclusion, we can not apply this estimate to assess the associated burden across behavioral health and medical surgical settings.

b. Section 482.13(f) Standard: Staff Training Requirements

Standard 482.13(f), previously entitled ''Restraint or seclusion: Seclusion and restraint for behavior management,'' has been revised to read ''Staff training requirements.'' This standard will specifically address the requirements that have been significantly changed or are new regarding staff training.

In section 482.13(f) Standard: Staff training requirements. Staff training requirements have been expanded to include various training specifications. While we have tried to minimize the burden which will be placed on hospitals in order to meet this requirement, we believe it is important for the provision of safe and effective restraint or seclusion use.

We require that before staff apply restraints, implement seclusion, perform associated monitoring and assessment of the restrained or secluded patient, or provide care for a restrained or secluded patient, the staff must be trained and able to demonstrate competency in the performance of these actions. We have revised the staff training requirements to address the following broad areas: Training intervals, training contents, trainer requirements, and trainer documentation.

When developing this final rule, we considered public comments regarding the impact associated with the requirement that all staff with direct patient contact be trained in the use of restraint or seclusion. Some argued that this broad requirement would entail training dietary, administrative, housekeeping, and other types of nonprofessional staff who are not direct care providers and not involved in the application or use of restraint or seclusion. To reduce burden and create a more reasonable requirement while assuring patient safety, we have mandated that only those staff who are involved in the application of restraint or seclusion or performing associated monitoring and assessment of, or providing care for restrained or secluded patients have this training. While we expect physicians and LIPs to be trained in the proper use of restraint or seclusion, we do not expect that they will be trained with the other hospital staff. Thus, we have not included physicians and LIPs in the burden associated with these requirements. Instead, we require the remaining hospital staff who have direct contact with patients must be trained in restraint or seclusion use.

We also considered commenters'suggestions that training be provided by a nationally-recognized training program, such as the Crisis Training Institute. Others asked that we provide a list of criteria to be covered in this training. In this final rule, we have specified broad topics to be covered in training, and have not required that staff be trained by an outside organization. We believe that in-house training may be more economical than sending staff off-site for instruction. However, hospitals would still have the option of sending either selected or all staff to outside training if they believe that this is warranted.

Thus, we have based our burden estimate on having the actual number of trainers attend such training from an outside organization one time. We believe that most facilities would, in turn, have these trained individuals function as program developers and trainers of the appropriate hospital staff. We believe in most instances this professional will be a registered nurse. Thus, we used $38.88 as the nursing hourly rate in this estimate.

Train-the trainer programs are the way many facilities provide staff instruction. The four day instructor certification program given by the Crisis Prevention Institute (CPI, INC.) costs $1,200 dollars in tuition plus travel, lodging, and participant salary (*http://www.crisisprevention.com*).

We estimate, on average, that roundtrip travel for each nurse will cost approximately $400 to cover the need for either local or distant travel, lodging for each nurse will costs approximately $120 per night × 3 nights, and the meals and incidental expenses (M&IE) will be approximately $50 per day depending upon the location within the designated state. Thus, we anticipate the cost to train one nurse per the 6,200 hospitals to be $1,200 for the course, an estimated $400 airfare based on location, $360 for 3 days lodging, $150 for 3 days M&IE, $112.50 for partial day M&IE, and $1,244.16 for the nurse's salarysat $38.88 per hour × 8 hours per day × 4 days. These expenses would total $466.66 per nurse per hospital. If all 6,200 hospitals were to send one nurse to such training, the total cost for the 6,200 hospitals would be $21,493,292.00.

Hours/est. salary/# of hospitals	Annual burden hours	Annual costs estimate
Off-site training of the trainer:		
Cost of course × 1 nurse		$1,200.00
Airfare × 1 nurse		400.00
Lodging × 1 nurse		360.00
M&IE × 1 nurse		262.50
Salary for 1 nurse × $38.88 per hr. × 8 hrs. day × 4 days each for a one time training	32	1,244.16
Total for 1 nurse per hospital × 6,200 hospitals	198,400	21,493,292.00

To be responsive to requests for more detail regarding our expectations and to assure staff competency, we have described the content to be covered during training. Given that most facilities already have some type of training program, as noted in many comments from hospitals, we believe that these requirements will only serve to refine existing programs, not mandate new ones. The current JCAHO standards which apply to approximately 80 percent of the Medicare- and Medicaid-participating hospitals address staff training and competence with respect to the use of restraint or seclusion at PC.12.30. The current JCAHO standard which applies to the hospital leadership's approach to the use of restraint for acute medical and surgical (non-psychiatric) care at PC.11.10 refers to staff orientation and education. In effect, these JCAHO standards already require training of this kind for staff involved with the application of restraint or seclusion. Thus, there may be some initial cost for revising

programs' materials to incorporate the elements specified in the regulation.

Hours/est. salary/# of hospitals	Annual burden hours	Annual costs estimate
Developing a new training program (20% of hospitals = 6,200 ÷ 20% = 1,240):		
1 clinical trainer @ $38.88 hr. × 40 hrs. on average one-time × 1,240 hospitals	49,600	$1,928,448.00
Total	49,600	1,928,448.00

Note: Salary data used in this estimate is based on the salary estimates reported on-line at *http://www.salary* com. Estimates based on median annual salary ($80,867.00 including benefits) for a Staff nurse-RN divided by 2,080 hours per year worked by a full-time employed Staff RN.

We require that each individual who will potentially be involved in restraint and seclusion of a patient have training in the proper techniques. According to the National Association of Psychiatric Health Systems (NAPHS), initial training in de-escalation techniques, restraint and seclusion policies and procedures, and restraint and seclusion techniques range from 7 to 16 hours of staff and instructor time.

Using data from the American Hospital Association's (AHA) 2004 Annual Survey, the average number of total full-time and part-time clinical employees per hospital are 248 and 113 respectively. Clinical employees include physicians and dentists, medical and dental residents and interns, other trainees, registered nurses, licensed practical (vocational Nurses), and nursing assistants. While we recognize this does not include clinical staff in such areas as rehabilitation services, this total of 361 persons per hospital should provide an estimate on which to base this analysis. We realize that some hospitals will have more or less employees in which to train.

Additionally, the CMS' OSCAR data, reveals the average number of beds per hospital is 160. We estimate that an average size hospital may have 361 staff persons who will require this training.

Hours/est. salary/# of hospitals	Annual burden hours	Annual costs estimate
Attendance in the training program:		
1 clinical trainer @ $38.88 hr. × 8 hrs. × 6,200 hospitals	49,600	$1,928,448.00
361 trainees × 16 hours per hospital × 6,200 hospitals	17,905,600	
Total	17,955,200	1,928,448.00

We require that each individual will receive annual updates to the training and that the annual training will also be documented. Again, according to NAPHS, annual updates are about 7 hours of staff and instructor time per each employee who has direct patient contact. Again, an average size hospital has 361 employees who have direct patient contact that must be trained in de-escalation techniques.

Hours/est. salary/# of hospitals	Annual burden hours	Annual costs estimate
Annual updates in the training program:		
1 clinical trainer @ $.38.88 hr. × 4 hrs. on average annually × 6,200 hospitals	24,800	964,224.00
361 trainees × 4 hours per hospital × 6,200 hospitals	8,952,800	
Total	8,977,600	964,224.00

Additionally, we required recordkeeping for documenting in each trained individual's personnel record that he or she has successfully completed training as discussed in Section V. of the preamble to this final rule. As noted there, we believe that such records are kept by the hospital in the normal course of business. Therefore, we do not believe that these requirements would have a significant economic impact on hospitals.

Hours/est. salary/# of hospitals	Annual burden hours	Annual costs estimate
Documenting attendance in the training program:		
1 clinical trainer @ $38.88 hr. × 5 minutes on average × 361 trainees annually × 6,200 hospitals	179,056	6,691,697.20
Total	179,056	6,961,697.20

Finally, we require that each hospital revise its training program annually as needed. We estimate this task to take approximately 4 hours annually per hospitals.

Hours/est. salary/# of hospitals	Annual burden hours	Annual costs estimate
Revising the training program:		
1 clinical trainer @ $38.88 hr. × 4 hours per average size hospital × 6,200 hospitals	24,800	964,224.00
Total	24,800	964,224.00

c. Section 482.13(g) Standard: Death Reporting Requirements

This requirement, previously an element in the interim final rule with comment period, has been revised to be a separate standard. In revising this to form a separate standard, we have made it applicable to all deaths associated with the use of restraint or seclusion throughout the hospital. We have added the requirements at § 482.13(g)(1)(i) that a hospital must report to CMS each death that occurs while a patient is in restraint or seclusion at the hospital, at § 482.13(g)(1)(ii) each death that occurs within 24 hours after the patient has been removed from restraint or seclusion, and at § 482.13(g)(1)(iii) that the hospital must report each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that the use of restraint seclusion contributed directly or indirectly to a patient's death.

At § 482.13(g)(2) and § 481.13(g)(3), we require that each death referenced in this section must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death. We believe that the number of deaths related to restraint or seclusion use are still under-reported. In October 1998, the *Hartford Courant* cited the results of a study that identified 142 deaths from seclusion and restraint use in behavioral health treatment facilities over the past 10 years. Since the Patients Rights CoP became effective in 1999, the annual total of patient deaths related to restraint and seclusion use has been reported to CMS as follows: 1999 (14), 2000 (34), 2001 (22), 2002 (19), 2003 (17), 2004 (24), 2005 (30), and 2006 (5) year-to-date respectively as of June 19, 2006. These numbers include deaths from seclusion or restraint use in behavioral health settings not the medical-surgical settings in the hospital.

Although our goal is to reduce the utilization of restraint or seclusion and associated deaths, we are aware that the actual number of deaths from seclusion and restraint use may increase due to the increased reporting requirements of deaths due to seclusion and restraint use in all treatment settings in the hospital. Thus, we anticipate there will be burden associated with this requirement due to the increased number of deaths that will be reported by the various units within the hospital. For the purposes of calculating burden, we are assuming the number of deaths based on current levels and are not considering the reduction in the number of deaths we expect to result from this regulation.

Given this historical data, we believe the number of reports certainly should average less than one per hospital per year (that is, the total number of deaths in 8 years (165) divided by the total number of hospitals 6,200 divided by 8 years equals .0033). Thus, we believe the impact associated with this provision (that is, making a telephone call and filling in a written form to report a death to the CMS) to be negligible.

We estimate that one clerical person would report the death to CMS and document the death in the patient's medical record. The burden associated with the completion of this task would be .25 (15 minutes divided by 60 minutes in one hour) × an average of 20 occurrences per year throughout the 6,200 hospitals, .25 × 20 = 5 hours. The estimated cost associated would be 5 hours × $.31 (that is, $18.88 hour divided by 60minutes per hour × 15 minutes = 4.71 × 20 occurrences per year = $94.20 annually).

Hours/est. salary/# of hospitals	Annual burden hours	Annual costs estimate
Reporting death to CMS and documenting in medical record:		
1 clerical person @ $18.88 hr. × 15 min. × average of 20 occurrences in hospital annually	5	$94.20
Total	5	94.20

Note: Salary data used in this estimate is based on salary estimates reported on-line at *http://www.salary* com. Estimates based on median annual salary ($39,190.00 including benefits) for an admitting clerk divided by 2,080 hours per year worked by a full-time employed admitting clerk.

2. Effect on Beneficiaries

The implementation of the Patients Rights CoP will serve to protect not only Medicare and Medicaid beneficiaries but all patients receiving care in all Medicare-participating hospitals (that is, short-term, psychiatric, rehabilitation, long-term, children's, and alcohol-drug), including small rural hospitals. With the finalization of standards a–g of the Patient's Rights CoP, we forsee better protection regarding notification of the patient's rights, exercise of the patient's rights with regard to his or her care, privacy and safety, confidentiality of the patient's records, and restraint and seclusion use. Thus, all patients will benefit from the hospital's focus on patients' rights. Through these protections, patient care can be delivered in an atmosphere of respect for an individual patient's comfort, dignity, and privacy. We also believe that implementation of this final rule will lead to a reduction in the numbers of restraint or seclusion related injuries and deaths in hospitals.

3. Effect on Medicare and Medicaid Programs

Given that hospitals have been required to comply with the regulations at § 482.13(a) through § 482.13(f) since 1999, we do not expect the implementation of the finalized Patients' Rights provisions to generate significant cost to the Medicare or Medicaid programs. We do not believe there will be any additional costs to the survey and certification program as compliance with this CoP will either be reviewed through a routine, nonaccredited hospital survey,

validation survey or as part of the existing complaint survey process for hospitals.

C. Alternatives Considered

We originally considered developing one set of very general requirements regulating restraint or seclusion use in all hospitals for all situations. However, based on public comments and recent concerns about restraint or seclusion use for behavior management situations, we concluded that one set of requirements did not afford patients with adequate protections. In addition, we noted that JCAHO has more prescriptive standards for behavioral health care accreditation than for hospital accreditation.

We considered recognizing only physicians as the individuals able to order restraints or seclusion. However, in recognizing that other types of practitioners provide a great deal of care in rural and frontier areas, we did not adopt that approach.

We considered keeping standards e and f separate as originally proposed. However, due to public comment we found it to be more prudent to address the use of restraint or seclusion in either medical-surgical or behavioral treatment contexts in a single standard.

We considered finalizing the training section as proposed. In turn, we planned to let hospitals establish, implement, and monitor their own training programs. However, industry concerns were the impetus for providing further direction regarding training. Additionally, we considered mandating training for physicians and other LIPs; however, the industry believed this was too prescriptive.

Regarding the timeframes in which a patient must be evaluated if restraint or seclusion is used to manage violent or self-destructive behavior, we considered more restrictive options including adopting the Pennsylvania Office of Mental Health policy that requires an onsite evaluation by a physician within half an hour of initiation of the intervention. However, we rejected this idea on the basis that it is unrealistic for rural areas because of geographical barriers and practitioner shortages, cost (as noted by commenters).

We considered adopting more restrictive requirements for the maximum time frames for the length of an order for restraint or seclusion. However, since there was no supporting literature or studies, we decided to adopt the approach and timeframes developed and articulated by JCAHO for its hospital accreditation and behavioral health care accreditation programs. These standards were developed by experts from the health care field and represent consensus on the approach and time frames for uses of seclusion or restraints. In addition, approximately 80 percent of the Medicare- and Medicaid-participating hospitals are already subject to these requirements through accreditation. Therefore, we believe it is reasonable to adopt requirements similar to those of JCAHO.

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

List of Subjects in 42 CFR Part 482

Grants programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the interim rule amending 42 CFR chapter IV published on July 2, 1999 **Federal Register** (64 FR 36070) is adopted as final with the following changes:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 1. The authority citation for part 482 continues to read as follows:

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

■ 2. Section 482.13 is revised to read as follows:

§ 482.13 Condition of participation: Patient's rights.

A hospital must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* (1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b) *Standard: Exercise of rights.* (1) The patient has the right to participate in the development and implementation of his or her plan of care.

(2) The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with § 489.100 of this part (Definition), § 489.102 of this part (Requirements for providers), and § 489.104 of this part (Effective dates).

(4) The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

(c) *Standard: Privacy and safety.* (1) The patient has the right to personal privacy.

(2) The patient has the right to receive care in a safe setting.

(3) The patient has the right to be free from all forms of abuse or harassment.

(d) *Standard: Confidentiality of patient records.* (1) The patient has the right to the confidentiality of his or her clinical records.

(2) The patient has the right to access information contained in his or her clinical records within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

(e) *Standard: Restraint or seclusion.* All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a

means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1) *Definitions.* (i) A *restraint* is—

(A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely; or

(B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

(C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

(ii) *Seclusion* is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

(2) Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient a staff member or others from harm.

(3) The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

(4) The use of restraint or seclusion must be—

(i) In accordance with a written modification to the patient's plan of care; and

(ii) Implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.

(5) The use of restraint or seclusion must be in accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.

(6) Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).

(7) The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

(8) Unless superseded by State law that is more restrictive—

(i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:

(A) 4 hours for adults 18 years of age or older;

(B) 2 hours for children and adolescents 9 to 17 years of age; or

(C) 1 hour for children under 9 years of age; and

(ii) After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) of this part and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient.

(iii) Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy.

(9) Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

(10) The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in paragraph (f) of this section at an interval determined by hospital policy.

(11) Physician and other licensed independent practitioner training requirements must be specified in hospital policy. At a minimum, physicians and other licensed independent practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion.

(12) When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention—

(i) By a—

(A) Physician or other licensed independent practitioner; or

(B) Registered nurse or physician assistant who has been trained in accordance with the requirements specified in paragraph (f) of this section.

(ii) To evaluate—

(A) The patient's immediate situation;

(B) The patient's reaction to the intervention;

(C) The patient's medical and behavioral condition; and

(D) The need to continue or terminate the restraint or seclusion.

(13) States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (e)(12)(i) of this section.

(14) If the face-to-face evaluation specified in paragraph (e)(12) of this section is conducted by a trained registered nurse or physician assistant, the trained registered nurse or physician assistant must consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under § 482.12(c) as soon as possible after the completion of the 1-hour face-to-face evaluation.

(15) All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion. Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored—

(i) Face-to-face by an assigned, trained staff member; or

(ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

(16) When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:

(i) The 1-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior;

(ii) A description of the patient's behavior and the intervention used;

(iii) Alternatives or other less restrictive interventions attempted (as applicable);

(iv) The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and

(v) The patient's response to the intervention(s) used, including the rationale for continued use of the intervention.

(f) *Standard: Restraint or seclusion: Staff training requirements.* The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) *Training intervals.* Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion—

(i) Before performing any of the actions specified in this paragraph;

(ii) As part of orientation; and

(iii) Subsequently on a periodic basis consistent with hospital policy.

(2) *Training content.* The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

(i) Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.

(ii) The use of nonphysical intervention skills.

(iii) Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.

(iv) The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia);

(v) Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.

(vi) Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation.

(vii) The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.

(3) *Trainer requirements.* Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.

(4) *Training documentation.* The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.

(g) *Standard: Death reporting requirements:* Hospitals must report deaths associated with the use of seclusion or restraint.

(1) The hospital must report the following information to CMS:

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death. ''Reasonable to assume'' in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.

(2) Each death referenced in this paragraph must be reported to CMS by telephone no later than the close of business the next business day following knowledge of the patient's death.

(3) Staff must document in the patient's medical record the date and time the death was reported to CMS.

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

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

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Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: November 16, 2006.

Michael O. Leavitt,

Secretary.

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