DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 482

[HCFA–3018–IFC]

RIN 0938–AJ56

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

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

ACTION: Interim final rule with comment.

SUMMARY: This rule introduces a new Patients' Rights Condition of Participation (CoP) that hospitals must meet to be approved for, or to continue participation in, the Medicare and Medicaid programs. This interim final rule with comment sets forth six standards that 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; confidentiality of his or her records; freedom from restraints used in the provision of acute medical and surgical care unless clinically necessary; and freedom from seclusion and restraints used in behavior management unless clinically necessary.

The issue of patients' rights has been a longstanding concern for the Health Care Financing Administration. In December 1997, we published a proposed rule that introduced the proposed revision of all hospital CoPs, including a new Patients' Rights CoP. Work to finalize the complete revision of the hospital CoPs continues; however, the Patients' Rights CoP is being finalized separately in an accelerated time frame as recent reports have evidenced a pressing need for the codification and enforcement of these fundamental rights. Of particular concern is the danger posed to patient health and safety by violations of basic patients' rights, such as freedom from restraints and seclusion.

The Patients' Rights CoP, including the standard regarding seclusion and restraints, applies to all Medicare- and Medicaid-participating hospitals, that is, short-term, psychiatric, rehabilitation, long-term, children's, and alcohol-drug.

DATES: *Effective Date:* These regulations are effective on August 2, 1999.

Comment date: Comments on 42 CFR 482.13(e) (Standard: Restraint for acute medical and surgical care) and (f) (Standard: Seclusion and restraint for behavior management) will be considered if we receive them at the appropriate address as provided in the **ADDRESSES** section, no later than 5 p.m. on August 31, 1999. We will not consider comments on provisions of the regulation that remain unchanged from the December 19, 1997 proposed rule or on provisions that were changed based on our consideration of public comments.

ADDRESSES: Mail comments (an original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–3018–IFC, P.O. Box 7517, Baltimore, MD 21207–0517.

If you prefer, you may deliver your comments (an original and three copies) to one of the following addresses:

Room 443–G, Hubert Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–16–03, 7500 Security Boulevard, Baltimore, MD 21244–1850

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–3018–IFC. Comments received timely will be available for public inspection as they are received generally beginning approximately 3 weeks after publication of a document, in Room 443–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

FOR FURTHER INFORMATION CONTACT: Monique Howard, OTR (410–786–3869); Julie Moyers (410–786–6772); Anita Panicker, RN, LCSW (410–786–5646); or Rachael Weinstein, RN (410–786–6775).

I. Background

A. General

On December 19, 1997, we published a proposed rule entitled ''Medicare and Medicaid Programs; Hospital Conditions of Participation; Provider Agreements and Supplier Approval'' at 62 FR 66726 to revise the entire set of conditions of participation (CoPs) for hospitals that are found at 42 CFR part 482. The CoPs are the requirements that hospitals must meet to participate in the Medicare and Medicaid programs. These CoPs are intended to protect patient health and safety and to ensure that high quality care is provided to all patients. The State survey agencies (SAs), under contract with us, survey hospitals to assess compliance with the CoPs. The SAs conduct these surveys using the *State Operations Manual* (SOM) (HCFA Publication No. 7). The SOM contains the regulatory language of the CoPs as well as interpretive guidelines and survey probes that elaborate on regulatory intent and give in-depth detail about how to maintain compliance. The SOM also outlines the survey process and provides guidance for State administration of the survey program. Under § 489.10(d), the SAs determine whether hospitals meet the CoPs and make corresponding recommendations to us about the hospital's certification, (that is, whether the hospital has met the standards required to provide Medicare and Medicaid services and receive Federal and State reimbursement).

Under section 1865 of the Act and § 488.5 (Effect of JCAHO or AOA accreditation of hospitals), hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA) are not routinely surveyed for compliance by the SAs but are deemed to meet the requirements in the CoPs based on their accreditation.

B. Why a Patients' Rights CoP Is Needed

In recent years, State surveyors, patient advocacy groups, the media, and the general public have brought complaints about hospitals violating patients' rights to our attention. These violations have consisted of denying or frustrating a patient's access to care, denying a patient's full involvement in his or her treatment, disregarding a patient's advance directives, denying a patient's access to his or her medical records, or inappropriately using seclusion or restraints. Particularly within the past year, the public, media, and the Congress have grown increasingly concerned about the need to ensure basic protections for patient health and safety in hospitals, especially with regard to the use of restraints and seclusion. The Hartford Courant, a Connecticut newspaper, heightened public awareness of this issue with a series of articles in October 1998 citing the results of a study that identified 142 deaths from seclusion or restraints use in behavioral health treatment facilities over the past 10 years. The majority were adolescent deaths.

C. Intent To Examine Restraint and Seclusion in Other Settings

Federal regulations for nursing homes already stress the right to be free of restraints, and over the past 10 years, significant strides have been made in

reducing inappropriate restraints used in this care setting. The Patients' Rights CoP will further extend these protections to another major provider of health care. However, this rule will not cover all care settings. As we finalized this rule, various stakeholders lobbied for a much broader application of the seclusion and restraint provisions. We are looking into the advisability of adopting a cross-cutting restraints and seclusion standard that would affect other kinds of health care entities with whom we have provider agreements and the inpatient psychiatric services for individuals under age 21 benefit. We are requesting comment on whether we should set forth the same requirements as promulgated in this rule or whether more stringent standards would be appropriate. For example, is the current standard for continual monitoring of patients in restraint adequate for children or should all restraints for children be monitored only by direct staff observation? In addition, we acknowledge that more stringent standards exist in the Medicaid requirements for restraint use in intermediate care facilities for the mentally retarded. We are requesting comments on whether we should consider the same requirements for the hospital setting. We plan to make a decision on our approach to restraints and seclusion across these other settings and services by the end of the winter.

Some patient advocates have asked that we go well beyond these entities and regulate care furnished by providers with whom we have no provider agreements or care provided in settings where we may lack statutory authority under the Social Security Act (the Act). Barring a legislative change, we cannot mandate a restraint and seclusion standard for those care settings or providers.

D. Conformance of Patients' Rights in Hospitals with the Consumer Bill of Rights and Responsibilities (CBRR)

In February 1998, President Clinton directed the Department of Health and Human Services (DHHS), among other departments, to bring our health care programs into compliance with the CBRR, as recommended by the Presidential Advisory Commission on Consumer Protection and Quality in the Health Care Industry. We are strongly committed to achieving this goal and are continuing to work to ensure that the important consumer protections articulated in the rights are available to our beneficiaries, whether Medicare or Medicaid, whether in managed care or fee-for-service settings.

We have endeavored to incorporate the protections of the Bill of Rights into the structures and operations of the providers and plans that provide care to our beneficiaries. Some of the rights included in the proposed section § 482.10 (now § 482.13) have direct correlates in the Consumer Bill of Rights, but other significant protections provided by the CBRR were not mentioned in the December 1997 proposed rule. Even though some of these protections currently exist due to requirements on hospitals that are not affected by the revisions to the CoPs, we have decided not to add new regulatory requirements to the Patients' Rights standard without subjecting them to a more public vetting than is provided by an interim final rule. We therefore ask for comment on the following additional consumer rights, which we believe would need to be incorporated in the CoPs in order to achieve compliance with the Bill of Rights:

- Information Disclosure: According to the Bill of Rights, consumers should receive the following information from health care facilities:
  + Corporate form of the facility (that is, public or private; nonprofit or profit; ownership and management; affiliation with other corporate entities).
  + Accreditation status.
  + Whether specialty programs meet guidelines established by specialty societies or other appropriate bodies (for example, whether a cancer treatment center has been approved by the American College of Surgeons, the Association of Community Cancer Centers or the National Cancer Institute).
  + Volume of certain procedures performed at each facility.
  + Consumer satisfaction measures.
  + Clinical quality performance measures.
  + Procedures for registering a complaint and for achieving resolution of that complaint.
  + The availability of translation or interpretation services for non-English speakers and people with communication disabilities.
  + Numbers and credentials of providers of direct patient care (for example, registered nurses, other licensed providers, and other caregivers).
  + Whether the facility's affiliation with a provider network would make it more likely that a consumer would be referred to health professionals or other organizations in that network.
  + Whether the facility has been excluded from any Federal health programs (that is, Medicare or Medicaid).

In addition, although not specifically mentioned in the CBRR, patient safety necessitates that all hospitals should publicly disclose whether and when they provide emergency services.

- Protection of Whistleblowers: Hospitals should be prohibited from penalizing or seeking retribution against health care professionals or other health workers for advocating on behalf of their patients. Individuals would be assured of this right in the Patients' Rights section.
- Respect and Nondiscrimination: While the preamble discusses the applicable Federal and State laws that prohibit discrimination, an explicit patient right to nondiscrimination is not currently included and would be added to the Patients' Rights section.

E. Other Patients' Rights

The remainder of the hospital CoPs and other Federal requirements provide patients with additional rights that do not appear in the new Patients' Rights CoP. The fact that we have not explicitly stated or cross-referenced these rights in the final rule does not mean that they are not available to the patient, or that they are in any way less important than the rights that this rule establishes.

Some of these rights are stated elsewhere in law or regulation. For example, various the civil rights laws uphold the patient's right to be free of discrimination. When the hospital enters into a provider agreement with us, a condition of that agreement is that the hospital will abide by the principles and requirements of title VI of the Civil Rights Act, as implemented in regulation at 42 CFR part 80; section 504 of the Rehabilitation Act of 1973, as implemented by 45 CFR part 84; the Age Discrimination Act of 1975, as implemented by 45 CFR part 90; and other requirements of the Office for Civil Rights of DHHS (see 42 CFR 489.10, Basic requirements). These requirements span all of the provider types with whom we hold an agreement and provide individuals with important protections against discrimination. A second relevant example is the patient's right that springs from the anti-dumping regulations at § 489.24 (Special responsibilities of Medicare hospitals in emergency cases). The anti-dumping regulations prohibit Medicare-participating hospitals with emergency medical departments from refusing to examine or to treat medically unstable patients.

While these two examples are clear cut instances where patients' rights are already codified, less visible rights also exist. For example, since the hospital is required to have adequate nurse staffing

to provide nursing care to all patients as needed (see § 482.23, Condition of participation: Nursing services), one could argue that the patient is thereby afforded the right to receive adequate nursing services and care. Or, since the hospital is required to have dietary menus that meet the needs of the patients (see § 482.28, Condition of participation: Food and dietetic services), the patient has the right to a diet that meets his needs.

We considered an approach that would have grouped all conceivable patients' rights within this CoP; however, the practical value of this approach is questionable as these elements are codified elsewhere, and an approach that attempts to be all-inclusive often inadvertently omits key elements. We believe that it suffices to say that we expect the hospital to honor and promote all of the rights and protections that Federal law and the hospital CoPs offer. The rights codified by this rule either do not appear elsewhere, or, as evidenced by reports, require a special emphasis.

II. Legislation

Sections 1861(e) (1) through (8) of 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 Medicare.

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.

III. Provisions of the Proposed Regulations

In our December 19, 1997 proposed rule, we proposed revision of the Medicare hospital CoPs in concert with Vice President Gore's Reinventing Government (REGO) initiative. The REGO initiative 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 strong emphasis on quality assessment and performance improvement.

In the proposed rule, we proposed setting forth a new Patients' Rights CoP in Medicare- and Medicaid-participating hospitals. The provisions of this CoP set forth minimum protections and promote patients' rights, including an individual's right to—(1) notification of his or her rights; (2) the exercise of his or her rights in regard to his or her care; (3) privacy and safety; (4) confidentiality; and (5) freedom from the use of seclusion or restraint of any form unless clinically necessary. In the preamble, we solicited comments on a more prescriptive approach to the use of restraints and seclusion and provided relevant examples.

Although we proposed codifying the new Patients' Rights CoP as § 482.10, in the final rule it is designated as § 482.13 to coordinate with the numbering system used in the current regulations. When the remaining hospital CoPs are finalized, we will renumber the standards in part 482.

Our commitment to the revision of the remaining hospital CoPs to focus on patient-centered, outcome-oriented care remains unchanged. We continue to work on analysis of the over 60,000 comments received on the proposed rule and will finalize the remaining hospital CoPs in the future.

IV. Comments and Responses

Of the 60,000 comments received on the December 1997 proposed rule, approximately 300 focused on the Patients' Rights CoP. Comments were received from hospitals, mental health treatment facilities, professional associations, accrediting bodies, SAs, patient advocacy groups, and members of the general public. Half of the comments, and the strongest opposition, came in response to the proposed fifth standard under Patients' Rights—seclusion and restraints. While many of the respondents did not favor prescriptive regulations that extended beyond the proposed regulations text, some welcomed more prescriptive language under the standard for seclusion and restraints.

A summary of the comments received on the five standards, major issues, and our responses follows.

A. Notice of Rights

We proposed that a hospital must inform each patient of his or her rights in advance of furnishing care and that the hospital must have a grievance process and indicate who the patient can contact to express a grievance.

Comment: Commenters indicated that what constitutes sufficient notification needs to be clarified. One commenter stated this requirement should be satisfied by providing written displays of patients' rights in the hospital lobby and in each patient's room, and in verbal or written form with initial and additional information included in the admission packet.

Response: We appreciate the suggestions of how and where patients' rights should be displayed or conveyed. However, hospitals will need flexibility to establish policies and procedures that effectively ensure that patients and their representatives have the information necessary to exercise their rights. These policies and procedures will need to address how, where, and when to notify patients of the full gamut of rights to which they are entitled under the Act. As hospitals assess the effectiveness of their proactive notification techniques, they need flexibility to continuously improve their performance in promoting patients' rights.

This CoP covers hospitals of varying sizes operating in a wide range of locations, serving diverse populations, with a variety of required notices; thus, flexibility and creativity to allow for the effective implementation of this requirement without undue burden is critical. Therefore, we are not including further prescriptive language detailing exactly where, how, when, and by whom this requirement must be carried out.

While we are committed to preserving flexibility on this point, we note that one method for efficiently handling aspects of this requirement may be to bundle notices with the existing information that must be provided to patients to fulfill Civil Rights requirements. The regulations implementing title VI of the Civil Rights Act of 1964, section 80.6(d), section 504 of the Rehabilitation Act of 1973 (45 CFR 84.8), and the Age Discrimination Act of 1975, section 91.32, require recipients of financial assistance from the DHHS to provide notice of their responsibility to comply with the appropriate nondiscrimination provisions and other pertinent requirements of the Office for Civil Rights. For a hospital that falls under this requirement, some patients' rights notices could be effectively posted next to these nondiscrimination notices. For some of the educational notices the patient will receive as part of the new Patients' Rights CoP, this public posting may be appropriate.

Comment: One commenter believed that the standards in the Patients' Rights CoP are generally reflected in common hospital practice; however, she objected to the general language that appeared at the beginning of the condition; specifically, the phrase, ''A hospital must protect and promote each patient's rights.'' This commenter was concerned

that the wording would be presented in isolation to juries during medical malpractice cases, and that it would be used to cover *all* legal and ethical rights. The commenter noted that a hospital staff person could not know or be responsible for providing this degree of information. The commenter suggested that the language be amended to read, ''A hospital is responsible to have policies and procedures in place which protect and promote the patient's rights as reflected in the following standards.''

Response: As stated earlier, we do expect the hospital to honor and promote each patient's rights, regardless of whether they appear in the Patients' Rights CoP. With respect to the commenter's concern that this statement will be taken in isolation and used in medical malpractice cases, we do not want to provide a foothold for frivolous cases. With that said, however, it could very well be that a patient who brings suit against a provider has a legitimate cause for concern or complaint because that provider failed to acknowledge his or her rights as established under these regulations. Such a case would generally require some substantiation and elaboration on specifically which right the provider failed to uphold. We are not persuaded that this language opens up an otherwise closed avenue for pursuing legal action. Accordingly, we are retaining this language.

Comment: One commenter noted that enumeration of the patient's rights is of little use if his or her only recourse is a grievance process that is controlled by the hospital. This commenter suggested adding a requirement that the patient also be notified that he or she could lodge a complaint with the State survey agency either after or during the course of the hospital stay, regardless of whether the patient decided to file a grievance with the hospital's system.

Response: The patient's right to file a complaint with or contact the accreditation body or the State to report an infraction on these rights is implicit; therefore, we do not believe it is necessary to add this to the regulations text. To address the commenter's concern, however, we will specify in the interpretive guidelines that patient notification of the grievance process must include the fact that the patient also may address his or her concerns to the State survey agency, regardless of whether he has first used the hospital's grievance process. Patients or residents of all Medicare-certified facilities have always had the ability to lodge complaints about the quality of care they receive with the State survey agency or HCFA, and nothing in this rule alters this opportunity. We will further specify that the patient be given a phone number and address for lodging a complaint with the SA.

Comment: Some commenters stated the proposed rule should account for the fact that in certain situations, the patient's age, condition, health problem, and emergency situation will inhibit the hospital's ability to notify the patient of his or her rights before the provision or discontinuation of care. Commenters believed that the rule should free hospital personnel from the responsibility of informing the patient of his or her rights if he or she is experiencing an emergency medical condition, is unconscious, or is at the hospital for a brief outpatient encounter.

Response: A hospital should make every effort to inform the patient of his or her rights before care provision or cessation of care. However, in some instances a patient's age, condition, health problem, or emergency situation does not allow the opportunity to communicate with the patient regarding his or her rights. For this reason, we are adding language to allow the hospital to communicate these rights to the patient's representative (as allowed under State law). In the absence of State law to cover particular health care decisions, the hospital may also communicate these rights to a legal representative whom the patient has appointed as an ''ad hoc'' decision maker in the event of temporary inability to make health care decisions. We still expect that as soon as the patient can be informed of his or her rights, the hospital will provide that information to the patient.

Comment: Some commenters stated that this discussion should be tailored to the patient's level of understanding or communication needs by using alternate means of communication (for example, audiotape, radio, sign language, and Braille, or other culturally competent vehicles), as necessary.

Response: Existing civil rights legislation (section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act (ADA)) emphasize the provision of effective aids, benefits, or services to individuals with disabilities. The ADA defines auxiliary aids and services as including qualified interpreters, notetakers, transcription services, written materials, telephone handset amplifiers, assistive listening devices, assistive listening systems, telephones compatible with hearing aids, closed captioning, telecommunications devices for deaf persons, videotext displays, or other effective methods of making aurally delivered materials available to individuals with hearing impairments; and qualified readers, taped texts, audio recordings, Brailled materials, large print materials, or other effective methods of making visually delivered materials available to individuals with visual impairments. Title VI of the Civil Rights Act of 1964 also requires recipients of certain public funds to serve persons who are ''Limited English Proficient'' (LEP). Translation of LEP documents, use of bilingual staff, and provision of interpreters are usually used to convey necessary information to LEP persons.

While we recognize the value of appropriate communication techniques, we do not offer further regulation in this area since existing laws ensure that appropriate attention will be given to providing information to those who require special accommodation based on their special needs.

Comment: Some commenters believed that the proposed rule needed to further define the patient's role and responsibility when being informed of his or her medical condition and that the standard should place more emphasis on discussion of prevention of complications and rehospitalization.

Response: The Patients' Rights CoP upholds the patient's right to full, informed involvement in his or her care. Under circumstances defined by State law, this right may also be exercised by the patient's legal representative on his or her behalf. We recognize that involvement in the plan of care and the choice of treatment option may be open to interpretation. We would like to clarify that this right to involvement in health care decisions cannot be equated with the ability to demand medically unnecessary treatments or care. The patient has the right to be informed of his or her status, to be involved in care planning and treatment, and to request and refuse treatment. The patient should be consulted about changes in care and treatment. Issues arising out of patient dissatisfaction with the hospital's response may be dealt with under the hospital's grievance process required under § 482.13(a); however, the patient may choose to lodge a complaint with the SA or accrediting body in addition to or instead of using the hospital's grievance system.

We agree that the patient's health and well-being are most likely affected by the degree of collaboration between the patient and physician. The patient should make every effort to bring medical problems to the attention of the physician in a timely fashion, provide information about his or her medical condition to the best of his or her knowledge, and work in a mutually respectful manner with the physician.

However, the patient's physical, mental, psychological, and emotional status may directly affect his or her ability to offer this degree of cooperation.

Comment: A commenter stated that a member of the interdisciplinary treatment team should document (in the medical record) that the patient's rights have been reviewed with the patient and whether the patient or his or her legal representative comprehends the information covered. A few commenters stated that social workers should notify patients of their rights at the time of the intake or screening interview.

Response: All of these suggestions have potential merit. However, as stated above, we believe it is necessary to provide the hospital with flexibility in developing policies and procedures that fulfill the requirement's intent, that is, to ensure that each patient's rights are protected.

Comment: A few commenters believed that no further details should be included in the regulation as more detail would add an unnecessary paperwork burden during the admission process while not guaranteeing improved quality of patient care.

Response: We have mandated neither the process that a hospital must use nor the extent to which these rights must be discussed as part of the admission process. In some cases, notification of these rights must occur later in the hospital stay to ensure that the patient's rights are protected. Hospitals will have the flexibility and accountability to determine how they can best ensure the protection of patients' rights.

Comment: A few commenters stated that the patient should be informed of the credentials, licensure, and professional qualifications, including certifications, of all personnel involved in his or her care through clear disclosure of this information on the hospital badge.

Response: We believe that this is an issue that hospitals should consider in developing their policies and procedures on notification of rights. We agree that it is important for patients to be aware of the identities of individuals who provide care in the hospital.

Comment: A few commenters suggested a patient should have the right to request care by a registered nurse (RN).

Response: Under the current hospital CoPs, hospitals are required to have 24-hour nursing services and an RN who supervises or evaluates the nursing care for each patient (§ 482.23(b)(3)). In addition, an RN must assign the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available (§ 482.23(b)(5)). We believe that the patient has a right to nursing care in hospitals; however, we disagree with the commenter's assertion of the patient's inherent right to request and receive the direct services of an RN. In rural areas where access to health care practitioners can be problematic, to mandate this requirement is impractical and burdensome. The current nursing services requirement provides for RN services for each patient through supervision of the nursing care provided. Existing regulations address and provide for the appropriate level of care in situations where a patient's condition warrants an RN's direct service.

Comment: One commenter agreed with our proposal that hospitals should have a formal grievance process for complaints and recommendations. However, we received more comments in opposition to this requirement. Those who opposed the provision believed it to be unnecessary, burdensome to establish, and limited in scope since it pertains only to patients' rights. A commenter noted that we did not specify how the hospital should plan to investigate complaints or the time frame within which hospitals would be required to respond to grievances.

Response: As we stated in the December 1997 proposed rule, whenever possible, we have attempted to adopt an outcome-oriented focus rather than establish process requirements. However, we believe that the establishment of a grievance process promotes patient empowerment in health care. We recognize that in and of itself this process may not be sufficient to resolve all potential sources of conflict. For example, in a situation where a patient disagrees with a course of treatment, the disagreement might be between the patient and an independent physician or health plan rather than with the hospital itself. Some issues may more logically be pursued under Medicare or Medicaid complaint processes or through a State mechanism. For example, hospitals already have procedures for referring Medicare beneficiaries' complaints about quality and concerns about premature discharge to peer review organizations for investigation and review. Whatever the type of concern, we expect that the hospital's grievance process will facilitate prompt, fair resolution. The grievance process should route each concern timely to the appropriate decision-making body. This expectation for coordination has been added to the text of the final rule.

As noted earlier, the interpretive guidelines will reiterate that the notification of a grievance process must include the fact that the patient has the right to file a complaint with the SA regardless of whether he or she chooses to use the hospital's process, and that he must be provided with the SA's phone number and address.

We considered the commenters' concerns about burden; however, to remain silent on general expectations for the grievance process could result in the absence of key ingredients that promote a meaningful, substantial process that addresses patients' concerns and promotes their rights. To promote the creation of an effective grievance process, in § 482.13(a)(2), we are establishing general elements that should be common to grievance processes across all hospitals. Development of more detailed strategies and policies to comply with the requirement will be left to the discretion of each hospital.

Exercise of Rights

B. We proposed That the Patient Has the Right To Be Informed of His or Her Rights and To Participate in the Development and Implementation of His or Her Plan of Care

Comment: Commenters stated that the patient should be informed if the treatment is experimental in nature and informed of the types of outcomes the hospital has encountered from the care. Commenters also suggested that the patient and his or her representative should be informed of the nature, expected outcome, and potential complications of treatment options that are going to be undertaken, as well as the potential outcomes if the treatment is refused.

Response: The hospital should foster an atmosphere that supports two-way communication with the patient regarding his or her care. We expect that the hospital will hold the responsible physician accountable for discussing all information regarding treatment, experimental approaches (hospitals are required to comply with 45 CFR part 46, protection of subjects of human research), and possible outcomes of care to promote quality care delivery. We believe it is unnecessary to codify the elements that must be discussed with a patient regarding development of his or her plan of care, or with whom among the hospital's staff or practitioners the patient must speak to develop that plan of care. Flexibility is necessary because discussions of treatment information will differ for each patient.

C. We Proposed That the Patient Has the Right To Make Decisions Regarding His or Her Care

Comment: Some commenters stated that the final rule should emphasize the patient participating fully in his or her care. Commenters believed that this could be achieved by allowing the patient to receive second opinions before starting a procedure that significantly differs from the pre-admission plan of treatment. These commenters stated that the final rule should require the patient to ''sign-off on treatment options'' and should acknowledge the patient's ability to refuse treatment and to refuse to participate in experimental research.

Response: We agree that the patient must be adequately informed of these options so that he or she can make educated decisions regarding his or her care. The requirement supports this emphasis and implicitly includes the commenters' concerns that a patient be able to refuse a certain treatment or participation in experimental research. However, in light of this comment, we decided to introduce a higher degree of specificity in the final rule. First, we noted that the patient's representative (as allowed under State law) can also exercise the right to make informed decisions on the patient's behalf. Second, we introduced a more detailed description of what the patient's right to make informed decisions entails. The patient has the right to be informed of his or her health status, to be involved in care planning and treatment (this includes pain management, as this aspect of treatment planning is often not discussed with patients), and to be able to request and refuse treatment. Abridgement of these patients' rights would be subject to the grievance process required by § 482.13(a). It is critical to note, however, that the standard does not provide the patient with the right to demand treatment or services that are not clinically or medically indicated.

D. We proposed that 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

Comment: One commenter wanted the issue of advance directives to be addressed at the time of the patient's Medicare enrollment rather than at the time of an acute care admission. This commenter stated that, ''Medicare beneficiaries could be required to designate their wishes with regard to 'do not resuscitate' (DNR) status and their surrogate healthcare decision-maker[s] as a condition of receiving the [Medicare] benefit. The CoP for the acute setting should address validating the beneficiary's 'pre-selected designations.'' '

Response: Section 1866(f) of the Act contains the provider requirements concerning the acknowledgment and handling of advance directives. The implementing regulations appear at 42 CFR part 489, Provider Agreements and Supplier Approval; specifically, at §§ 489.100 through 489.104. When we developed the December 1997 proposed rule, we believed that it was appropriate to reference advance directives in the Patients' Rights CoP, consistent with other Medicare provider CoPs (for example, existing regulations for nursing homes and home health agencies). The regulations governing advance directives and their implementation are not directly affected or under debate in this rule. This rule is not the appropriate venue for addressing the more general issue of advance directives, which spans provider types and is not specific to the hospital CoPs.

Comment: A commenter stated that the language regarding advance directives should encourage increased communication about and access to palliative care for the terminally ill. Another commenter believed that detailed advance directives should apply to inpatients, but not outpatients.

Response: Regarding the commenter's concern that advance directives should apply to inpatients not outpatients, section 1866(f) of the Act and implementing regulations at § 489.102 require that the hospital give each individual (1) written information concerning an individual's rights under State law to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives, and (2) written policies of the provider or organization with respect to the implementation of advance directives. Section 1866(f)(2)(A) specifically notes that this information must be provided when an individual is admitted as an inpatient to a hospital; therefore, the hospital need not provide this information to those who are receiving outpatient services.

We appreciate the commenter's suggestion that the language about advance directives incorporate increased information about and access to palliative care for the terminally ill. However, neither the statute nor the existing regulations about advance directives discuss linking increased discussion of and access to palliative care with the advance directives requirement. Further, as noted earlier, the proposed rule did not contemplate amending the existing advance directives requirements. We do believe, however, that referencing the patient's right to formulate and have hospital staff comply with advance directives in the new Patients' Rights CoP will lead to increased communication regarding end-of-life decisions, pain management, and other palliative care.

Comment: One commenter believed that a hospital should be required to check and adhere to advance directives, including those pertaining to psychiatric emergencies, by incorporating the appropriate training to ensure patients are knowledgeably consenting and by including quality improvement efforts to study the issue.

Response: We believe that existing regulations at §§ 489.100, 489.102, and 489.104 already address these concerns. The final rule cross-references these citations and supports the existing regulatory expectation. However, the commenter touched upon a point that merits additional response: specifically, that advance directives are not limited to end-of-life decisions. In the mental health setting, a patient may form advance directives that relate to what should be done if he or she experiences a psychiatric crisis. In an advance directive, a person with a mental disorder leaves instructions as to his or her health care when he or she no longer has decision-making capacity. These instructions may include, for example, the name of the health care proxy, the name of the facility in which one wishes to receive services, the name of the provider from whom one wishes to receive treatment, names of medications and dosages that work best, and the methods to be used to de-escalate a crisis to avoid the use of seclusion and restraint. In the interpretive guidelines, we will further describe the aspect of advance directives that relates to psychiatric emergencies to place a greater emphasis on and encourage responsiveness to these situations.

E. Privacy and Safety

We Proposed That the Patient Has the Right to Privacy and To Receive Care in a Safe Setting

Comment: One commenter stated that language of the preamble that referred to the patient's respect, comfort, and dignity was not included in the regulations text.

Response: We believe that patient respect, dignity, and comfort are the foundation of the expectations outlined

by the regulation—freedom from all forms of abuse and harassment, the right to privacy, and the right to care provided in a safe setting. As we have noted earlier, these standards are intended to provide protection for the patient's physical and emotional health and safety. Respect, dignity, and comfort would be components of an emotionally safe environment. This point will be reinforced when we prepare corresponding interpretive guidelines to implement this final rule.

Comment: Commenters agreed with the concept of the patient's right to privacy but believed that the term ''privacy'' is broad and undefined. Some stated that ''personal privacy'' should be defined and a statement should be included to relieve hospitals of the responsibility of providing each patient with a private room, since ''privacy'' could be misinterpreted to mean that a patient has a right to a private room.

Response: We understand the commenters' concerns but are not including a description of ''privacy'' in the final rule. We intend to address the accommodation of privacy rights through the interpretive guidelines, as that venue permits a more thorough explanation of expectations.

We agree that ''privacy'' does not mean that each patient has a right to a private room. However, even if a patient is in a semiprivate room, the hospital should provide a patient with privacy by steps such as pulling curtains closed for exams and requesting visitors to leave the room when treatment issues are being discussed.

Comment: Some commenters believe ''personal privacy'' and ''receive care in a safe setting'' should not be combined since they are separate issues.

Response: We agree and have separated the two elements under the standard ''Privacy and Safety.''

F. We Proposed That the Patient Has the Right To Be Free From Verbal or Physical Abuse or Harassment

Comment: Some commenters wanted the word ''free'' to be replaced by ''protected'' and the phrase ''from hospital staff'' included in the standard. One commenter observed that patients can misinterpret hospital staff's helpful verbalizations as abusing and harassing. Commenters believed that this section should clarify that verbal warnings or physician contact with a patient, visitor, or employee, that are reasonably necessary to protect others from intimidation or threat of violence will not be construed as verbal or physical abuse. Other commenters wanted the regulation to express sensitivity to the fact that hospital personnel will not always be able to anticipate the potential for harassment and harm inflicted by another patient.

Response: While the patient is under the hospital's care and on its property, the hospital is responsible for ensuring the patient's health and safety and his or her physical, emotional, and psychological well-being. We recognize that there is always a chance a patient can misinterpret staff's intentions. We expect that hospital staff would intervene in a timely, appropriate manner to correct any misinterpretations in a timely, appropriate manner, if this situation were present.

In the final rule, we have amended the language to address all forms of abuse rather than just physical and verbal abuse. We recognize that any sort of abuse, including verbal, physical, psychological, sexual, and emotional, is unacceptable.

G. Confidentiality of Patient Records

We Proposed That the Patient Has the Right to Confidentiality of His or Her Clinical Records

Comment: A commenter stated that without specific language regarding privacy and confidentiality, research efforts may be stifled by the regulation.

Response: Presumably, the commenter is concerned that without a clear statement regarding the confidentiality of patient records, patients would be reluctant to participate in medical research if asked. We have maintained the proposed language regarding confidentiality; however, we agree with the commenter's assertion that patients need to have a clear understanding of how a hospital operationalizes this requirement. We will discuss this further in interpretive guidelines.

Comment: A commenter questioned whether the stated language is expressing a concern for each patient's ability to access his or her records or whether the language views a hospital's tendency to ''systemically'' frustrate individuals' legitimate attempts to gain access to medical records as a violation of the requirement.

Response: We believe it is each patient's inherent right to have access to his or her clinical record, as well as to have his or her clinical record kept confidential. We are setting forth this requirement in the final rule.

Comment: A few commenters noted that there was no definition provided for the term ''reasonable'' when it was used to describe the time frame within which the hospital must provide the patient with access to information in his or her records. They believed that this lack of specificity would make it difficult for JCAHO to determine hospitals' compliance with the standard. A few commenters believed that the regulation should state that the patient has a right to a copy of his or her records within 4 hours of an inpatient stay and within 48–72 hours for a patient who has been discharged. A few commenters believed that the regulations text should clearly account for the impact of variations in location of data, record complexity, urgency, and staff workload.

Response: Regarding the definition of ''reasonable,'' we believe that ''reasonable'' means that the hospital (1) will not frustrate the legitimate efforts of individuals to gain access to their own medical records, and (2) will actively seek to meet these requests as quickly as its recordkeeping system permits. We have included these expectations in the regulations text at § 482.13(d)(2).

We agree with the commenters who asserted that we should account for the impact of various factors such as location of data, urgency, and staff workload. Rather than attempting to stipulate time frames within the regulation that would cover all possible combinations of factors, we are simply retaining the word ''reasonable.'' We trust that if the patient believes that he is being subjected to unreasonable treatment as he tries to obtain a copy of his medical records, he will use the hospital's grievance process or will report difficulties to the SA or JCAHO. While setting a concrete time frame might provide a better measuring stick for performance, it would not adequately account for the kinds of variation that are apt to occur in different hospital settings.

Comment: Some commenters suggested that the rule be expanded to state, ''In accordance with local and State laws, the patient has a right to confidentiality of his or her clinical and personal information and records and a right to a copy of his or her medical record or information in his or her medical record within a reasonable time frame.''

Response: This comment could have several meanings. The idea of deferring to local and State law could apply to the confidentiality provision, the access requirement, the reasonable time frame, or all three. Specifically, it could be construed to mean that—

(1) ''The patient's right to the confidentiality of his or her record is governed by State or local law (rather than Federal law).'' Currently, DHHS's position on this point is to defer to State

rules that are more protective of privacy than Federal rules whenever possible.

While our intention is that the Patients' Rights CoP protects record confidentiality to the greatest extent possible, we recognize that some disclosure may be necessary. For example, in the December 1997 proposed rule, we proposed under the revised Information Management CoP that the patient's medical information must be available to all authorized professional personnel providing medical care to the patient. If the patient's care is to be well integrated and planned, those who are providing the various professional services involved in the patient's treatment may need to review the patient's medical status and history. It is expected that there will be management choices and policies determining what uses and disclosures of patient information are authorized, and that there will be administrative, management, and technical safeguards to ensure that only persons using records for authorized purposes may have access to them. For example, the release of the patient's record may occur if the patient is transferred to another facility, to comply with the provisions of Federal law and State law (where State law is not inconsistent with Federal law), when allowed under third party payment contract, as approved by the patient, and when inspection by authorized agents of the Secretary is required for the administration of the Medicare program.

(2) ''The patient's right to access his or her record should be governed by State and local law.'' A discussion of DHHS's position is in order. The general policy position of the DHHS on this topic is set out in ''Confidentiality of Individually-identifiable Health Information, Recommendations of the Secretary of Health and Human Services, pursuant to section 264 of the Health Insurance Portability and Accountability Act of 1996,'' in which the Secretary recommended Federal legislation to protect the rights of patients with respect to their health information.

The policy recommended there is that the patient should be allowed to inspect and copy health information about himself or herself held by providers and payers, but that providers and payers could, in their discretion, withhold information from the patient under very narrowly defined circumstances:

- The information is about another person (other than a health care provider) and the holder determines that patient inspection would cause sufficient harm to another individual to warrant withholding.
- Inspection could be reasonably likely to endanger the life or physical safety of the patient or anyone else.
- The information includes information obtained under a promise of confidentiality (from someone other than a health care provider), and inspection could reasonably reveal the source.
- The information is held by an oversight agency and access by the patient could be reasonably likely to impede an ongoing oversight or law enforcement activity.
- The information is collected in the course of a clinical trial, the trial is in progress, an institutional review board has approved the denial of access, and the patient has agreed to the denial of access when consenting to participate.
- The information is compiled principally in anticipation of, or for use in, a legal proceeding.

DHHS's policy also provides that those holding these health care records be permitted to deny inspection if the information is used solely for internal management purposes and is not used in treating the patient or making any administrative determination about the patient, or if it duplicates information available for inspection by the patient.

The DHHS's policy sets forth the expectation that in general, patients should be able to see and copy their records, and that recordholders should only be able to deny access to the portion of the record that meets the aforementioned criteria. The recordholder should redact the portions allowed to be denied and should give the patient the rest of the information. The accompanying discussion of DHHS's policy recommendations supports patient access to his or her own records. At least 31 States explicitly provide this right by law.

While we acknowledge the provider's right to exercise judgment in the release of a patient's record in these narrow instances, we firmly believe that a patient cannot take an active, meaningful role in his or her health care decisions if he or she is not allowed to know what is happening to his or her own body or mind. If he or she cannot comprehend that information, then it should be available to his or her representative (as allowed under State law), who then acts on his or her behalf. The patient's right to be informed of his treatment, his health status, and his prognosis is just that—his inherent right, to be exercised by the individual or at his or his representative's (as allowed under State law) discretion. We believe that this right is best supported by giving the patient access to his or her own record in all but the most extreme cases.

(3) ''The patient will receive his or her medical records within the time frame prescribed by State or local law.'' We would defer to either State or local guidance on this point.

The criteria we have set out above, that would describe circumstances that might limit access by patients to their hospital medical records, are not being incorporated into this final rule. Rather, we are raising them now as examples of the narrow areas in which providers should exercise discretion. Once we have reviewed the comments, we will consider whether further guidance is necessary.

Comment: One commenter stated the regulation should require records to be supplied at a fair market rate.

Response: Pricing must not create a barrier to the individual receiving his or her medical records. Records should be supplied at a cost not to exceed the community standard. If State law establishes a rate for the provision of records, State law should be followed. However, in the absence of State law, the rate charged by organizations such as the local library, post office, or a local commercial copy center that would be selected by a prudent buyer can be used as a comparative standard.

We are finalizing the requirement as proposed and believe that charging excessive fees for copies of a patient's medical record would constitute a violation of the Patients' Rights CoP as this practice could be used to frustrate the legitimate efforts of individuals to gain access to their own medical records. We expect that we would receive and investigate complaints if hospitals charged excessive fees for medical records.

Comment: Some commenters stated that consideration should be given to risk management issues involved in the release of incomplete medical records.

Response: We are unsure whether the commenter is referring to a closed record that may be incomplete or to a request for a copy of a current, open record that, until the patient is discharged, will be incomplete. In either situation, we believe it is a patient's inherent right to have access to his or her clinical record. A hospital may decide to provide a staff member to review the record with the patient as necessary to minimize misunderstandings and respond to concerns.

H. Seclusion and Restraint

(1) We Received Approximately 150 Comments Regarding the Proposal That Patients Have the Right To Be Free From the Use of Seclusion or Restraint, of Any Form, as a Means of Coercion, Convenience, or Retaliation by Staff

Comment: None of the commenters voiced an objection to the addition of this standard under Patients' Rights.

Response: Since we proposed the rule in 1997, interest in the use of seclusion and restraint and its consequences has increased markedly. Part of this heightened awareness is due to media attention devoted to this topic. One of the most controversial series of newspaper reports appeared in October 1998 in Connecticut's *Hartford Courant.* The articles cited the results of a study that identified 142 deaths from seclusion and restraint use in behavioral health treatment facilities, including psychiatric hospitals and psychiatric treatment units in general hospitals, over the past 10 years. Restraint use has also been covered in the broadcast media and has been investigated by the General Accounting Office. All of this attention has generated a great deal of concern for patient safety and well-being within the public, private, and regulatory sectors.

While we find the reports of deaths associated with restraint use disturbing, we are equally concerned with the impact that restraint use has on acute and long-term care patients. The prevalence of injuries and accidents involving restraint is difficult to gauge. If manufacturers learn of a death or serious injury caused by a medical device, they must report it to the Food and Drug Administration (FDA). Device user facilities (hospitals, nursing homes, outpatient treatment facilities, outpatient diagnostic facilities) must report a death of one of their patients caused by the medical device to FDA and the manufacturer, and a serious injury to the manufacturer only. No other entities are required to report to FDA or the manufacturer.

Research indicates that the potential for injury or harm with the use of restraint is a reality. In a 1989 article published in the Journal of the American Geriatrics Society, Evans and Strumpf pointed to an association between the use of physical restraint and death during hospitalization (Evans, LK and Strumpf, NE: Tying down the elderly: A review of the literature on physical restraint. J Am Geriatr Soc (1989) 37:65–74; also see Robbins, LJ, Boyko E, Lane, J, et al.: Binding the elderly: A prospective study of the use of mechanical restraint in an acute care hospital. J Am Geriatr Soc (1987) 35:290; Frengley, JD and Mion, LC: Incidence of physical restraints on acute general medical wards. J Am Geriatr Soc (1986) 34:565; Strumpf, NE and Evans, LK: Physical restraint of the hospitalized elderly: Perceptions of patients and nurses. Nursing Research (1998) 37:132.) The FDA estimates that at least 100 deaths from the improper use of restraints may occur annually. Mion et al. further noted that, ''Some evidence exists that the use of physical restraints is not a benign practice and is associated with adverse effects, such as longer length of hospitalization, higher mortality rates, higher rates of complications, and negative patient reactions. Physical restraints have a detrimental effect on the psychosocial well-being of the patient'' (see Mion et al.: A further exploration of the use of physical restraints in hospitalized patients. Jour Am Geriatr Soc (1989) 37:955; Schafer, A: Restraints and the elderly: When safety and autonomy conflict. Can Med Assoc J (1985) 132:1257–1260).

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

While we acknowledge that in some emergency situations the use of restraint may be the least potentially harmful way to protect the individual's safety or that of others, the patient's right to be free from restraint is paramount. Restraint use should be the exception to the rule, not a standard practice. The question that arises is how we and the medical community, with the common goal of the well-being of each patient, can eliminate the inappropriate use of restraint and can ensure the safety and health of the patient in emergency situations where a restraint is applied. In considering how to achieve these goals, we refer to the article by Evans and Strumpf:

''* * * the consideration of the anticipated length of time in restraint, goals of care, and the likely outcome for the patient become extremely important questions to answer in those instances where restraints are contemplated or in use * * * Further, more attention to staff education regarding selection of appropriate restraints by type and size and their proper application and monitoring seems to be warranted if restraint-related accidental injuries and deaths are to be avoided.'' (J Am Geriatr Soc (1989) 37:70).

In its Safety Alert of July 15, 1992, the FDA echoed the need for training to decrease the incidence of deaths and injuries involving restraining devices. The FDA suggested that institutions provide in-service training for staff as regularly as possible, including a demonstration of proper application of restraint. Given the stated need for training if accidental injuries and deaths are to be avoided and the use of alternative measures promoted, we have added language to the final rule that will require a training program on restraint for staff. We have also noted that these training programs should review alternatives to restraint and seclusion, to teach skills so that staff who have direct patient contact are well equipped to handle behaviors and symptoms as much as possible without the use of restraints or seclusion.

In the final rule, we have added the word ''discipline'' to the standard statement to read, ''The patient has the right to be free from the use of seclusion or restraint, of any form, as a means of coercion, discipline, convenience, or retaliation by staff.'' Discipline is not an acceptable reason for secluding or restraining a patient. In the treatment environment, it is impossible to distinguish between ''discipline'' and ''punishment.''

Another addition to the final rule are definitions of ''physical restraint,'' ''drug that is used as a restraint,'' and ''seclusion.'' We believe that codifying the definitions of these terms will provide a clear legal basis for the enforcement of these standards.

We have decided upon a division of the restraint and seclusion standard in the final rule. As we began work on the final rule, we discovered a pattern of differences between an intervention used in the provision of acute medical and surgical care and one used to manage behavioral symptoms. This difference was situation-specific rather than necessarily linked to provider type. While the definition of ''restraint'' spans care settings, the circumstances and expected outcomes for restraints use vary.

In the final rule, we have attempted to differentiate between situations where a restraint is being used to provide acute-level medical and surgical care and those where restraint or seclusion is used to manage behavior.

This approach is similar to that adopted in existing standards that JCAHO has created for restraint and seclusion. When a restraint is applied in the course of acute medical and surgical care, the intervention is generally not undertaken because of an unanticipated outburst of severely aggressive or destructive behavior that poses an imminent danger to the patient and others. In medical and surgical care, a restraint may be necessary to ensure that an intravenous (IV) or feeding tube will not be removed, or that a patient who is temporarily or permanently mentally incapacitated will not reinjure him or herself by moving after surgery has been completed. Using a device such as an IV arm board to provide medication that, if skipped, would cause the patient considerable injury or harm may be the least restrictive intervention that accomplishes the necessary administration of the medication. The use of a restraint in this circumstance is necessary for the patient's well-being (to receive effective treatment) when less restrictive interventions, such as keeping the patient's arm free and mobile have been determined to be ineffective.

Depending on the patient's diagnosis and health status, whether the acute medical and surgical care patient requires constant monitoring while restrained or can be monitored and reassessed at regular intervals is a matter of clinical judgment. Additionally, seclusion is not an intervention selected to help with the provision of medical or surgical services; therefore, references to seclusion have been removed from the final standard that appears as subsection (e).

A critical point to remember is that these standards are not specific to the treatment setting, but to the situation the restraint is being used to address. For example, if a hospital has a wing for psychiatric patients where it uses restraint or seclusion to manage behavior, it must meet the restraint and seclusion behavior management standard for those patients.

The use of restraints or seclusion to manage behavior is an emergency measure that should be reserved for those occasions when an unanticipated, severely aggressive or destructive behavior places the patient or others in imminent danger. While different factors may precipitate this type of psychiatric, behavioral, and physical outburst for an individual patient, the need for rapid assessment and continuous monitoring is applicable in each case.

Accordingly, we are accepting commenters' suggestions to regulate the time frames within which certain actions must occur in the behavior management scenario. We are adopting the concept of time-limited orders that appears in JCAHO's 1999 Hospital Accreditation Standards. Specifically, the intent statement for standard TX.7.1.3.1.8 provides that written orders for restraint or seclusion for behavioral health patients are limited to 4 hours for adults, 2 hours for children and adolescents ages 9 to 17, or 1 hour for patients under age 9. These time frames were created for JCAHO's use by a committee of experts in the field. We stress, however, that these time frames represent the maximum time intervals for which each order can be written. Physicians or licensed independent practitioners may write orders for shorter increments of time. A licensed independent practitioner is any individual permitted by law and by the hospital to provide care and services, without direction or supervision, within the scope of the individual's license and consistent with individually granted clinical privileges. Additionally, under regulation, while the patient is being restrained or secluded, his or her status must be continually monitored, assessed, and reevaluated, with an eye toward releasing him or her from the restraint or seclusion at the earliest possible time. We believe that these factors will ensure that the patient is restrained or secluded for as brief a time as possible. In addition, we are requiring that if the restraint or seclusion order is written by a physician or licensed independent practitioner other than the ''treating'' physician, the treating physician must be consulted as soon as possible The ''treating'' physician is the physician who is responsible for the management and care of the patient. We believe that this is important because the ''treating'' physician may have information regarding the patient's history which may have a significant impact on the selection of restraint or seclusion as an intervention. For example, the patient may have a history of sexual abuse and restraints or seclusion may actually cause psychological harm.

JCAHO also states in its explanation of intent for standard TX.7.1.3.1.7 that each licensed independent practitioner best carries out his or her responsibility when he or she participates in daily reviews of restraints and seclusion use related to his or her patients. We are adopting a parallel philosophy by specifying in the regulation that an order for restraint or seclusion may only be renewed in the previously mentioned increments (4 hours for adults; 2 hours for patients ages 9 to 17; 1 hour for patients under 9) for up to a total of 24 hours—to that point, the practitioner must reevaluate his or her patient face-to-face before writing a new order. We believe that it is appropriate to recognize JCAHO's work in this area and maintain consistency between Federal and accreditation standards when possible.

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 standard for restraint use in the provision of acute medical and surgical services and the standard for restraints and seclusion use for behavior management are built on the same foundation; however, the behavior management standard contains more rigorous requirements for the timeliness of actions that must be taken by a physician or other licensed independent practitioner who is granted authority under State law and by the hospital to order restraints use or seclusion. The creation of two restraints standards does not represent any lessening in our commitment to restraint reduction and, as much as possible, elimination in both the provision of acute care and behavior management situations. The distinction does acknowledge, however, that it may not be reasonable to have identical standards for two very different situations. The absence of time frames for the acute care standard should not be construed as permission to restrain patients without timely interaction with the physician or other licensed independent practitioner who is permitted by the State and the hospital to order restraint. When restraint is used to provide acute medical or surgical care, we still expect the patient to be continually assessed, monitored, and reevaluated by hospital staff. The patient's care needs will dictate how frequently reassessment by a physician or other licensed independent practitioner is necessary. In any case, we expect the discontinuation of the restraint at the earliest possible time.

(2) We Proposed That if Seclusion and Restraints Are Used (Including Drugs Used as Restraints), They Must be Used in Accordance With the Patient's Plan of Care, Used Only as a Last Resort, in the Least Restrictive Manner Possible, and Removed or Ended at the Earliest Possible Time

Comment: One commenter suggested that there needs to be better understanding of why seclusion and restraints are used, and development of efforts to reduce their use. However, this commenter did not believe further prescriptive Federal regulation is necessary.

Response: There is a need to understand why seclusions and restraints are used; however, the reasons behind the use of restraints have been studied and to some extent documented (see Strumpf NE and Evans, LK: Physical restraint of the hospitalized elderly: Perceptions of patients and nurses. Nursing Research (1988) 37:132–137; Evans LK and Strumpf NE: Tying down the elderly: A review of the literature on physical restraint. Jour Amer Geriatr Soc (1989) 37:65–74; Janelli, LM: Physical restraint use in acute care settings. J Nurs Care Qual (1995 Apr) 9(3) 86–92.) Various studies substantiate that restraints are being used when alternate solutions are available (see Donat, DC: Impact of a mandatory behavior consultation on seclusion/restraint utilization in psychiatric hospitals. J Behav Ther Exp Psychiatry (1998 March) 29:1, 13–9; Dunbar, J: Making restraint-free care work. Provider (1997 May) 75–76, 79; and Moss, RJ: Ethics of mechanical restraints. Hasting Center Report (1991 Jan–Feb) 21(1):22–25.)

While restraints reduction and education programs are underway and should be encouraged, we believe that it is critical to reinforce appropriate restraints reduction by acknowledging the patient's right to be free from restraints except when the use of a restraint is the least restrictive option that will provide the greatest benefit to the patient (that is, the risks associated with the use of the restraint are outweighed by the risk of not using it). When used to manage behavior, the use of restraint or seclusion is only an emergency measure and requires careful assessment and monitoring to ensure patient safety.

Comment: Some commenters suggested that this regulation display consistency between HCFA and JCAHO requirements.

Response: We understand and appreciate concerns about consistency between HCFA and JCAHO standards. As mentioned above, we have modified the final rule to introduce separate standards to address restraint or seclusion used for behavior management and restraint used in the provision of acute medical and surgical care. This change reflects the differing emphases contained within JCAHO's current requirements. As we further develop the guidelines, we will continue to work closely with JCAHO.

Comment: A number of commenters suggested that the terms ''as a last resort'' should be replaced with, ''when medically indicated,'' or, ''when medically necessary,'' or ''when other appropriate measures have been found to be ineffective.''

Response: We have replaced the term, ''as a last resort'' with ''when other less restrictive measures have been found to be ineffective.'' We reaffirm that restraints use should not be a standard practice, and restraints should be used only when other less restrictive alternatives are ineffective to protect the safety of the patient or others.

Comment: A few comments suggested including ''and hospital policy'' after ''patient's plan of care'' to link patient care to the hospital requirements.

Response: To meet the restraint and seclusion requirements, hospitals may develop their own policies focusing on alternatives to seclusion and restraint, the underlying patient condition, and the discontinuation of seclusion or restraint as soon as possible. However, it seems redundant to require hospitals to then follow their own policies. Our primary concern is that the requirements of the regulation be met. Ensuring the connection between the regulations and standards of practice and smooth implementation is part of the hospital's responsibility to meet the CoPs. Accordingly, we are not adopting the commenter's suggestion.

Comment: One commenter suggested that less restrictive and more restrictive devices should be held to different standards.

Response: We do not want to apply unnecessary multiple standards when the overarching principle is that the patient has the right to be free from restraints, whether artificially or scientifically classed, that restrict normal movement or access to his or her body. We recognize the difference between an arm restraint applied to enable the provision of needed medication versus a posey vest or four point restraint; however, when their use is avoidable, we expect that the hospital will refrain from using any of these devices. When this intervention is absolutely necessary to the safety and well-being of the patient or others, the hospital does have the ability to use these devices.

We expect hospital policies and procedures regarding all use of restraints or seclusion to comply with the same fundamental standard: At the very least and before all else, the intervention should do no harm. Any intervention must be made in the context of an ongoing loop of assessment, intervention, evaluation, and reintervention. A corollary principle is that the greater the risks associated with an intervention, the more careful and thorough the assessment must be.

Comment: Seclusion and restraint should never be used simultaneously and should not cause physical pain to the patient.

Response: We are strengthening the final rule by specifying that physical restraints may not be used in combination with seclusion unless the patient is either (1) continually monitored face-to-face by an assigned staff member; or (2) is continually monitored by staff using both video and audio equipment. This monitoring must be in close proximity to the patient.

We agree that the use of a restraint should not harm or cause pain to the patient. We will address this topic in the interpretive guidelines. We believe that these concepts should be covered as part of the staff training in the proper use of seclusion and restraint.

A slightly different issue is the use of a drug as a restraint in combination with a physical restraint or seclusion. As acknowledged elsewhere in this preamble, drugs may be used for a variety of purposes and may have positive value as part of a well-planned therapeutic strategy. Some are appropriate given the individual's plan of care and specific situation. The regulation supports the patient's right to be free from drugs that are used to restrain the resident in the absence of medical symptoms or for the purpose of discipline, convenience, retaliation, or coercion; however, we do not wish to introduce regulations that might block the strides made to appropriately medicate patients who are, for example, in pain or clinically depressed.

Comment: A few commenters suggested that the requirement for patient records include alternative approaches attempted before the use of seclusion and restraints.

Response: Documentation included in the patient's medical record was discussed in the proposed rule of December 1997 at proposed § 482.120(a), the Information Management CoP. The proposed Information Management CoP requires

recording the diagnosis, comprehensive assessment and plan of care, evaluations, consent forms, notes on treatments, nursing, medications, reactions, a summary report with provisions for follow-up care, and any relevant reports. The CoP also requires that revisions to the plan of care be documented in the patient's record. Accordingly, as the general requirements are addressed in another section that will be addressed in the hospital CoP rule when it is published as final, we are not adopting the commenter's suggestion. However, we expect that the medical record will contain information on less restrictive measures that may have been considered before the selection of seclusion or restraint use. In the interpretive guidelines, however, we will go into further detail about the expectation surrounding the requirement that restraint or seclusion only be used after less restrictive interventions are shown to be ineffective. The interpretive guidance will describe what surveyors should look for in examining compliance with this standard.

Comment: Data showing the use of seclusion and restraints and any patient injuries incurred as a result should be reported.

Response: It is possible that States and localities may have requirements for reporting these incidents. Additionally, Federal law requires that deaths involving restraining devices be reported to the FDA, and that both deaths and serious injuries associated with restraint use be reported to the device's manufacturer. However, this reporting does not cover the situations where patients are suffocated or critically injured during physical holds. To be more inclusive, we are adding a § 482.13(f)(7) (under the behavior management standard) that requires each hospital to report to us 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 as result of restraint or seclusion. HCFA will track the reports of deaths from restraints or seclusion occurring in hospitals. HCFA will use this information to (1) authorize onsite investigations (complaint surveys) of these hospitals in accordance with the current complaint investigation process; and (2) inform the Federally-mandated Protection and Advocacy (P&A) entity in the respective State or territory. Protection and Advocacy programs are Congressionally authorized (in accordance with 42 U.S.C. 10101 *et.seq.*) to access facilities and to investigate abuse and neglect complaints. Furthermore, we are soliciting comment on the pros and the cons of requiring the reporting of serious injury or abuse related to the use of restraints or seclusion, as well as the type of injury or abuse that would be reported, and the process whereby these incidents would be reported.

Comment: Some commenters suggested the need for hospitals to develop and implement hospital-based performance and outcome measures for restraints and seclusion.

Response: We are not mandating the development of these standards at this time. However, we expect that a hospital, as part of its internal quality assessment and performance improvement program, will evaluate itself in patient care activities that have potential safety issues, including the use of restraints and seclusion.

Comment: Commenters stated the need to provide periodic educational sessions for hospital staff on the proper use of seclusion and restraint in compliance with HCFA guidelines.

Response: We agree. We are adding a requirement that as part of ongoing training, staff who have direct patient contact are trained in the proper and safe use of seclusion and restraints, as well as trained in techniques and alternatives to handle the symptoms, behaviors, and situations that have historically prompted restraint or seclusion. For example, topics of training could include cardiopulmonary resuscitation techniques, methods for appropriately positioning a restrained patient's head and body to ensure proper respiration and circulation, or methods for monitoring cardiovascular status. We will provide a more detailed description of safe, appropriate restraining techniques in the interpretive guidelines.

Research on restraints supports education as the key component in decreasing or eliminating the use of seclusion or restraints (see Stilwell, EM: Nurses' education related to use of restraints. (1991 Feb) 17(2) 23–6; Cruz, V: Research-based practice: Reducing restraints in acute care setting. (1997 Feb) 23(2)31–40; and Janelli, LM: Acute/critical care nurses' knowledge of physical restraints-implications for staff development. (1994 Jan–Feb) 10(1)6–11). As noted earlier, education may also be crucial in efforts to reducing and eliminating restraints-related injuries.

Comment: A commenter requested further clarification of the definition of ''restraint,'' the types of restraints, and the types of situations where these measures should be used. Commenters wanted HCFA and the medical community to collaborate in developing these working definitions, giving consideration to differences in patient care issues that are age and population specific in acute care hospitals, behavioral health treatment facilities, and nursing homes. These commenters requested inclusion and clarification of when the use of side rails constitutes a restraint and a discussion of leather versus soft restraints.

Response: We have provided definitions of ''physical restraint,'' ''drug that is used as a restraint,'' and ''seclusion'' in the final rule and plan to provide further guidance in the interpretive guidelines in the SOM. To adequately respond to commenters' questions, we will respond in three parts.

1. Physical Restraint

The functional definition of ''physical restraint'' parallels existing guidance regarding restraints found in HCFA's SOM Appendix P (nursing home requirements). A restraint is a restraint regardless of setting. A posey vest is no less restrictive when applied in a hospital than when used in a nursing home.

Similarly, we are not categorizing varieties of physical restraints, such as soft versus leather. An object is a restraint by functional definition; that is, when it restricts the patient's movement and access to his or her body. Under this definition, all sorts of devices and practices could constitute a restraint. For example, tucking a patient's sheets in so tightly that he or she cannot move is restraining him or her. In that instance, a sheet is a restraint. One has to examine how the device or object is being used. Putting up side rails that inhibit the patient's ability to get out of bed when he or she wants to constitutes a restraint. In summary, we have adopted a functional definition that does not name each device and situation that can be used to inhibit an individual's movement simply because we believe that this approach is counterproductive. One could not possibly capture all scenarios or devices in regulation, and a functional approach promotes looking at individual situations. From our experience with nursing homes, we know that many people look for a clear-cut list of restraints. We believe that clinicians will agree, however, that each case is different. A device that acts as a restraint for one individual may not inhibit the movement of another. Accordingly, we have incorporated a definition that focuses on function for the individual.

Concerning leather and soft restraints, patient safety and comfort are primary

considerations in selecting a restraining technique or device. We do not feel qualified to comment on one being preferable to the other, but would offer that restraints in general should be avoided as much as possible.

2. Drug Used as a Restraint

We have noted in the regulations text at § 482.13(e)(1) and § 482.13(f)(1) that a drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition. Before discussing the concepts behind this definition, we would point out that the language that precedes this definition clearly sets forth that the patient has the right to be free from seclusion or restraint, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. This right is provided under both the acute medical and surgical care provisions and the behavior management provisions.

Even when there are medical indications for the use of a drug as a restraint, we believe that the precautions outlined in the regulation are necessary to protect the patient. The definition contains a phrase that merits some discussion—''and is not a standard treatment for the patient's medical or psychiatric condition.'' As stated elsewhere, we do not want to unintentionally interfere with the administration of drugs that are part of a patient's therapeutic plan of care—for example, for a patient with a psychiatric diagnosis, a mood or behavior-affecting drug may be part of the patient's overall care plan. To address this consideration, we added language to address what we see as the primary point the standard hopes to address—not the drug that is being used as an integrated part of the care plan, but the drug that is not part of a standard treatment for the patient's medical or psychiatric condition.

3. Seclusion

The definition adopted, ''the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving,'' is an adaptation of JCAHO's definition.

Comment: We proposed a more prescriptive set of requirements for restraints and seclusion in the preamble to the proposed rule. Many commenters cited a potential burden, inefficiency of care, expense, and safety issues that may arise as a direct result of mandating physician consultation to evaluate for restraint utilization, to write orders every 2 hours for pediatric patients or every 6 hours for adult patients (instead of every 24 hours), to have face-to-face contact, and to have primary authority to initiate written orders for seclusion and restraints. A commenter pointed out that the proposed rule will exceed the current law in his State. In that State, seclusion and restraint orders may be issued by either a physician, Ph.D., licensed clinical psychologist, or master's prepared registered nurse. One commenter believed that frequency of assessment should be based on the patient's presenting factors. Many commenters believed the proposed rule would be restrictive and impractical, thereby encouraging false documentation and limiting the ability of the registered nurse in ''sound clinical decision making.''

Response: We acknowledge the perceived burden of a more prescriptive set of standards. As we explained above, in this rule we have attempted to differentiate between situations where a restraint is being used to provide acute-level medical and surgical care and those when restraint or seclusion is used to manage behavior.

To address the concerns about the burden of requiring all of these functions to be performed by the physician, as well as the comment that some States permit other licensed independent practitioners to order restraint and seclusion, we have changed the final regulation to indicate the possible involvement of these other types of professionals as permitted by State law and hospital policy. However, we are interested in receiving comments on whether we should adopt more restrictive requirements that would allow only physicians to order restraints or seclusion for behavior management.

We considered the other commenters' concerns about the restrictiveness and impracticality of the requirements, the adverse effect that the requirements might have on the RN's ability to make sound clinical judgments, and the potential for falsification of records. We disagree with these comments on several counts. First, the RN's decision-making skills and judgment are a cornerstone of good patient care. This rule is not curtailing the RN's role in patient care. Second, the standard for restraint use for acute medical and surgical care maintains flexibility. We have avoided being overly prescriptive in this standard because of the need for sound clinical judgment in meeting the patient's individual care needs. In the provision of acute medical and surgical care, we agree with the commenter who observed that patient assessment should be based on his or her presenting condition. (Earlier, we described the rationale for codifying a greater degree of specificity for the standard for restraint and seclusion in behavior management.) Regardless of the situation that is presented to the hospital, the nurse's observation and intervention in patient care remains critical. Concerning the falsification of records, we see no connection between the requirements we are establishing in this rule and an increase in the behavior.

Comment: A commenter wanted to prohibit PRN orders and mandate 15-minute checks on restrained patients. Some responders believed that there should not be a defined time limit for restraint use, while a few believed that this limit should be instituted. One commenter believed that patients under age 18 should be in seclusion or restraint for shorter periods than adults. One responder suggested a maximum of 16 hours.

Response: We agree that PRN orders should never be used with or as a part of seclusion and restraints, and this concept has been added to the final rule. The use of PRN orders for seclusion and restraints would allow a facility to indiscriminately seclude or restrain patients. As noted earlier, in the acute medical and surgical care standard, the need for monitoring continually versus periodic checks is a determination that will largely be correlated with the individual patient's diagnosis, treatment, and health status. Basically, the determination of frequency of monitoring must be made on an individual basis. However, we are mandating that restraints or seclusion be ended at the earliest possible time based on *continuous* assessment and reevaluation of the patient's condition. We expect that this assessment would include items such as vital signs, circulation, hydration needs, level of distress, and agitation. In interpretive guidance, we will specify what is meant by ''continuous assessment and reevaluation of the patient.''

In response to the commenter who believed in differentiating between the length of restraint for adults and patients under the age of 18, we have adopted JCAHO's approach to time-limited orders for restraints or seclusion. Concerning the comment that restraint should be limited to 16 hours, we understand the desire to put some sort of a cap on the amount of time that an individual can be restrained. However, we found no precedent for a 16-hour or any other time-specific cap, and we believe that it is clinically ill-advised to set an absolute maximum on how long an individual can be restrained. As discussed earlier, we have indicated that orders for physical

restraint and seclusion may be renewed in the previously mentioned increments for up to a total of 24 hours. At that point, the physician or licensed independent practitioner who ordered the use of restraints or seclusion must see his or her patient in person to determine whether the issuance of a new order is appropriate. The requirement that patients who are restrained for behavioral purposes are continually assessed, monitored, and reevaluated, combined with the regulatory expectation that restraints use will be discontinued at the earliest possible time, should ensure that restrained patients are released as soon as they can commit to safety and no longer pose a threat to themselves or others.

While the regulation stresses the minimal use of restraint or seclusion, when these steps are necessary, the staff's training should provide a good groundwork for ensuring that staff know how to meet each patient's basic needs. As a result of their training, staff should be equipped to assess, monitor, and reevaluate each restrained patient as well as provide care to meet basic needs.

Comment: Suggestions were made that nurses should be allowed (1) to receive verbal or telephone orders from physicians who are prescribing restraint or seclusion orders and (2) to use ongoing assessment and a standardized restraint protocol.

Response: Current requirements at § 482.23(c)(2)(i) allow nurses to receive verbal or telephone orders. In addition, many States have laws regarding telephone orders. We agree that professional staff should be able to use standard seclusion or restraint protocols, in accordance with medical standards of practice and hospital policies and procedures that are consistent with these regulations. If a hospital and medical staff develop and authorize the use of this protocol for emergency situations, it would meet the requirement that restraints be used in accordance with the order of a physician or other licensed independent practitioner who is approved by the State and the hospital to issue this order. We will explain this further in interpretive guidelines. We expect that the nurse or other professional who initiates the protocol will contact the appropriate physician at the earliest possible time to obtain a verbal order for the restraint or seclusion intervention.

Comment: Provisions need to be made for the emergency application of restraints.

Response: We agree. Hospitals may develop an emergency protocol approved by the medical staff to be used in emergency situations in a manner consistent with these regulations.

Comment: Commenters stated that we are singling out the use of psychopharmacological drugs in the overall proposed rule. One commenter asked that references to psychopharmacological drugs be removed from the CoP.

Response: We agree that there is no need to specify ''psychopharmacological'' drugs and have removed the term. Any drug that alters mood, mental status, or behavior can be used as a restraint depending on the situation.

Comment: Many comments centered around linking the valid use of restraints (including drugs used as restraints) to the patient's plan of care and the hospital's policy.

Response: The use of restraints must be linked to the patient's modified plan of care, and we have put this language in the regulation. We refer to the ''modified'' plan of care to reinforce our expectation that restraint or seclusion should not be a standard response to a particular behavior or situation. The use of these interventions is an emergency measure that temporarily protects the safety of the patient and others; however, it is not a long-term solution for handling problematic behavior.

If restraints are used, their use must be in accordance with a physician's order (or other licensed independent practitioner's order, as noted earlier) and the patient's modified plan of care; used in the least restrictive manner possible; used in accordance with appropriate restraining techniques; use only when other appropriate measures have been found to be ineffective to protect the patient or others from harm; and ended at the earliest possible time. The patient's treating physician must be consulted as soon as possible, if the treating physician did not order the restraint. In addition, the condition of the restrained patient must be continually assessed, monitored, and reevaluated.

Comment: A commenter believed that no further details need to be included in the regulation as it only increases the paperwork burden for the hospital while not guaranteeing improved quality of patient care.

Response: We have adopted more prescriptive requirements based on recent public health concerns, as noted above. The paperwork aspect of both the acute medical and surgical restraint use and the behavior management restraints and seclusion are minimal. As other factors, such as the professionalism and training of staff, will affect patient outcomes, we agree that a detailed process does not necessarily in and of itself guarantee quality of care. However, we believe that we have established a framework in regulations that promotes the patient's right to be free of restraints and seclusion and protects him or her when their use is instituted.

Comment: One commenter asserted that particularly in psychiatric institutions, restraints and seclusion can be used to prevent patients from filing complaints or taking steps to initiate discharge. The commenter further noted that even those patients who are not in seclusion may effectively be prevented from using the phone to notify family or a primary physician of their hospitalization by an unscrupulous provider. To address this situation, the commenter recommended that we include the patient's right to request that a family member of his or her choice and his or her physician be notified promptly of his or her admission to the hospital.

Response: In the final rule, we have added a requirement that addresses this right.

General Comments

Comment: Recommendations were made for us to provide more guidance on the specific documentation hospitals are required to provide to surveyors to indicate compliance and, ultimately, for us to be aware of how these regulations may impact patient safety.

Response: We intend to issue interpretive guidance that will elaborate on the hospital's responsibilities, what the surveyors should evaluate to determine compliance with this requirement, and the extent to which the use of seclusion or restraints in each individual instance provides demonstrable evidence that the intervention is clearly tied to the individual patient's plan of care. Through our on-site survey presence in initial certification surveys, recertification surveys and the investigation of complaints, HCFA will monitor how well hospitals are meeting these new standards.

Comment: A commenter suggested the use of measurement and assessment processes that would identify opportunities to reduce the risk associated with restraint use through introducing preventive strategies, innovative alternatives, and process improvement.

Response: We think this is an excellent suggestion; however, we are not mandating specific measures or assessment protocols. We expect a hospital, through its quality assessment

and performance improvement activities, to assess itself in this regard.

Comment: A commenter suggested including the right to nondiscriminatory treatment—which should include a prohibition against discrimination on the basis of mental or physical disability and socioeconomic status.

Response: As a result of their receipt of Federal funds, Medicaid-and Medicare-participating hospitals are already prohibited from discriminating on the basis of race, color, or national origin (under title VI of the Civil Rights Act of 1964), age (under the Age Discrimination Act of 1975), and disability (under section 504 of the Rehabilitation Act of 1973). In addition, the Americans with Disabilities Act protects persons with disabilities from discrimination.

The regulations governing the Medicare provider agreement recognize these protections and discuss them at § 489.10(b). Specifically, this section, entitled ''Basic requirements,'' requires the provider to meet the applicable civil rights requirements of title VI of the Civil Rights Act of 1964, as implemented by 45 CFR part 80, which provides that no person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subject to discrimination under any program or activity receiving Federal financial assistance. Section 489.10(b) also requires compliance with section 504 of the Rehabilitation Act of 1973 (which provides protection against discrimination to qualified persons with disabilities), the Age Discrimination Act of 1975 (which provides protection against discrimination based on age), and other pertinent requirements of the Office for Civil Rights of the Department of Health and Human Services. Moreover, if a facility is funded under title VI or title XVI of the Public Health Service Act, it is prohibited from denying services to persons unable to pay for needed services if the persons are seeking emergency services and reside in the hospital service area or if those persons are eligible under the uncompensated services provision of the Act. The facility is also prohibited from discriminating based on method of payment.

V. Provisions of the Final Rule

For reasons specified in the preamble, we are codifying the Patients' Rights CoP within the current hospital CoPs under Subpart B—Administration at § 482.13. The six standards to the CoP will set forth minimum protections and will promote patients' rights. Changes have been made to strengthen the proposed regulation and are set forth as follows.

The first standard, Notice of Rights, states, ''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.'' This standard also requires that the hospital have a grievance process and indicate who the patient can contact to express a grievance. The minimum elements that must be common to all hospital grievance processes are specified.

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. The Exercise of Rights standard sets forth the patient's right to make decisions regarding his or her care and the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with those directives, in accordance with § 489.100 (Definition), § 489.102 (Requirements for providers), and § 489.104 (Effective dates). We have added a requirement that the patient has the right to have a family member or representative of his or her choice and his or her physician notified promptly of his or her admission to the hospital.

The third standard, Privacy and Safety, has been changed so that ''personal privacy'' and ''receive care in a safe setting'' could be made into two separate elements under this standard as requested by commenters. The final regulation states that ''The patient has the right to personal privacy,'' and, ''The patient has the right to receive care in a safe setting.'' We have altered the requirement that the patient has the right to be free from verbal or physical abuse and harassment to state that the patient has the right to be free from all forms of abuse or harassment.

The fourth standard, Confidentiality and Patient Records, contains the provisions of the proposed rule; specifically, the right to the confidentiality of his or her record and the right to access information contained in his or her clinical records within a reasonable time frame. To this standard, we have added a requirement stating that 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 recordkeeping system permits.

The fifth standard, Restraint for Acute Medical and Surgical Care, codifies the patient's right to be free from both physical restraints and drugs that are used as a restraint that are not medically necessary or are used as a means of coercion, discipline, convenience, or retaliation by staff. The rule defines ''restraint,'' ''physical restraint,'' and ''drug used as a restraint.'' In accordance with commenters' suggestions, we removed the term ''psychopharmacological'' from the standard to acknowledge that a wide range of drugs may be used as a restraint.

The regulation states that a restraint can only be used when less restrictive interventions have been determined to be ineffective. It also acknowledges the ability of licensed independent practitioners authorized by the State and the hospital to write orders for restraints. The regulation states that the patient's treating physician must be contacted, as soon as possible, if the restraint is not ordered by the patient's treating physician. We have added language that mandates that restraints must never be written as a standing order, or on an as needed basis (that is, PRN). The final rule states that restraint use must be in accordance with a written modification to the patient's plan of care; in the least restrictive manner possible; in accordance with safe and appropriate restraining techniques; and selected only when other less restrictive measures have been found to be ineffective to protect the patient or others from harm. The standard regarding restraint use related to acute medical and surgical care also requires that the condition of the patient in restraints must be continually assessed, monitored, and reevaluated; the restriction of patient movement or activity by restraints be ended at the earliest possible time; and all direct care staff must have ongoing education and training in the proper and safe use of restraints.

The last standard, Seclusion and Restraint for Behavior Management, contains many of the same elements stated in the fifth standard (related to restraints used in acute medical and surgical care) but goes further by discussing the use of seclusion and provides specific requirements for the monitoring and evaluation of a secluded or restrained patient for behavior management.

This standard provides that seclusion or restraint for behavior management can only be used in emergency situations if it is needed to ensure the patient's physical safety, and less restrictive interventions have been

determined to be ineffective. This standard also provides that seclusion or restraint use must be in accordance with the order of a physician or other licensed independent practitioner who is permitted by the State and hospital to order seclusion or restraint use. It also requires that the patient's treating physician be consulted, as soon as possible, if the restraint or seclusion is not ordered by the patient's treating physician. The final rule also states explicitly that the requirement for restraint or seclusion use for behavior management will be superseded by existing State laws that are more restrictive.

This standard provides that seclusion or restraints may not be ordered on a standing or PRN basis. The regulation requires a physician or other licensed independent practitioner to see and evaluate the need for restraint or seclusion within 1 hour after the initiation of this intervention.

The final rule sets limits for each written order for physical restraints or seclusion based on a patient's age. For adults, the written order is limited to 4 hours; for children and adolescents (age 9–17), the written order is limited to 2 hours; for patients under age 9, the written order is limited to 1 hour. The final rule states that the original order may only be renewed for up to a total of 24 hours. After the original order expires, a physician or licensed independent practitioner (if permitted by State law) must see and assess the patient before issuing a new order.

The final rule states that any restraint or seclusion use must be in accordance with a written modification to the patient's plan of care, implemented in the least restrictive manner possible, in accordance with appropriate restraining techniques, and selected only when less restrictive measures have been found to be ineffective to protect the patient or others from harm.

The standard discusses restraints and seclusion used in combination, and provides that they may not be used simultaneously unless the patient is continually visually monitored, in person, by an assigned staff member, or is continually monitored by staff by audio and video equipment. This audio and video monitoring must occur in close proximity to the patient. It also states that the condition of the patient who is in restraints or seclusion must continually be assessed, monitored, and reevaluated and that the restriction of patient movement or activity by seclusion or restraint use must be ended at the earliest possible time.

The rule also requires that all staff who have direct patient contact have ongoing training in both the proper and safe use of seclusion and restraints and alternative techniques and methods for handling the behaviors, symptoms, and situations that traditionally have been treated through restraint and seclusion. While we are not detailing the sorts of behaviors, symptoms, and situations here, we plan to further describe them in the interpretive guidelines that will implement this regulation.

Finally, the regulation requires the hospital to report to us 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 as a result of restraint or seclusion.

VI. Regulatory Impact Statement

A. Overall Impact

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

The RFA (5 U.S.C. 601 through 612) requires agencies to analyze options for regulatory relief for small entities. Consistent with the RFA, we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, we treat most hospitals and most other providers, physicians, health care suppliers, carriers, and intermediaries as small entities, either by nonprofit status or by having revenues of $5 million or less annually. Individuals and States are not included in the definition of a small entity.

Also, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. That analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds. Although the provisions of this interim final rule with comment do not lend themselves to a quantitative impact estimate, we do not anticipate that they would have a substantial economic impact on most Medicare-participating hospitals. However, to the extent the rule may have significant effects on providers or beneficiaries, or be viewed as controversial, we believe it is desirable to inform the public of our projections of the likely effects of the proposals.

The Unfunded Mandates Reform Act of 1995 requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits for any rule that may result in an annual mandated expenditure by State, local, and tribal governments, in the aggregate or by both the private sector, of $100 million. This rule has no mandated consequential effect on State, local, or tribal governments, or the private sector and will not create an unfunded mandate.

In December 1997, we proposed to revise all of the hospital CoPs in concert with Vice President Gore's REGO initiative. The REGO initiative 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 to place a stronger emphasis on quality assessment and performance improvement.

Within this newly revised CoP, we proposed the establishment of a Patients' Rights CoP for hospitals that contains rights not addressed in the current provisions. We solicited comments on the Patients' Rights CoP and received strong support for its establishment. There was consensus among the public, mental health advocacy groups, media, and the Congress that we should move toward establishing such a CoP. This consensus was prompted by serious concern about improper care of patients in the hospital setting, with regard to all aspects of patient care, including the use of seclusion and restraint. These factors led us to set forth this final rule with comment to ensure the protections of patients' rights in the hospital setting, including the right to be free from the use of seclusion and restraint. We believe that this regulation will broaden the consumer's role in safeguarding and participating in his or her care.

Consumer protections are of vital importance in the hospital setting. The recent focus of efforts such as the formulation of the Consumer Bill of Rights and Responsibilities points to the public acknowledgment of the important role that each individual is called upon to play in his or her care. We believe that Medicare CoPs must foster each individual's rights as an informed consumer and decision maker. Accordingly, we are promoting the

concepts in the Consumer Bill of Rights and Responsibilities, and we are asking the public for comments on incorporating additional consumer rights into the hospital CoPs in order to promote compliance with the Consumer Bill of Rights.

B. Anticipated Effects

1. Effect on Hospitals

Since the Patients' Rights CoP set forth below is a newly established CoP, we have no factual reports, studies, or data to aid in the development of cost or savings estimates. However, we believe most hospitals are already fulfilling many of the requirements of this regulation due to State requirements, and hospital policies and procedures, especially existing policies and procedures to meet the Life Safety Code and Physical Environment requirements of the current hospital CoP, which cover safe environment issues. Therefore, there may be no significant increase in burden to most hospitals.

Given the shift toward regulatory flexibility, for the most part, we are not prescribing the exact process hospitals must follow to meet the regulatory requirements regarding Patients' Rights. However, there are several provisions that will impact hospitals to a greater or lesser degree. Specifically, hospitals will have to establish policies and procedures necessary for compliance with this regulation: notification of rights, exercise of rights, privacy and safety, confidentiality, and patient access to records. Hospitals will have to develop a grievance process and ensure that staff are provided with 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 were treated through the use of restraints or seclusion. In addition, hospitals will have to report to the appropriate HCFA regional office any deaths that result from restraint or seclusion use for behavior management.

Regarding the grievance process, hospitals may use different approaches to effectively meet this CoP. We are setting forth the general elements that should be common to grievance processes across all hospitals, but we are not explicitly delineating strategies and policies to comply with the requirement. Also, we are setting forth more detailed, prescriptive requirements than were contained in the proposed rule for the use of seclusion and restraint for behavior management situations. Despite the potential burden associated with the implementation of some portions of this regulation, we believe that by recognizing and attending to patients' rights, hospitals may find improvements in patient collaboration and satisfaction with care, a reduction of patient-initiated lawsuits regarding care, and through the hospital's own grievance process, find a wealth of information to guide quality improvement efforts.

We expect hospitals to develop different approaches to compliance with the Patients' Rights CoP based on their varying resources and patient populations, differences in laws in various localities, and other factors. However, even in situations where the regulation could result in some immediate costs to an individual hospital (that is, developing and implementing a process to notify patients of their rights and allow patients to exercise their rights), we believe that the changes that the hospital would make would produce real long-term economic benefits to the hospital (that is, a reduction in lawsuits). It is important to note that because of the flexibility afforded hospitals to implement this regulation, the extent of the economic impact on individual hospitals will vary and is subject in large part to their decision-making. The impact will also vary according to each hospital's current policies and procedures and level of compliance with existing State law and regulations.

Overall, we believe that the benefits of complying with the Patients' Rights CoP will far outweigh the costs involved. We also note that with regard to the restraint and seclusion standards for both acute medical and surgical care and behavior management, there should be no significant additional burden for, at least, the 80 percent of Medicare-participating hospitals accredited by JCAHO since the requirements are modeled on JCAHO's standards for both their hospital accreditation program and their behavioral health care accreditation program. For the other 20 percent of hospitals that are nonaccredited, there may be some one-time costs associated with developing policies and procedures for restraint and seclusion use. However, we believe that the benefits far outweigh the costs because, from a risk management viewpoint, clear policies will protect the hospital from situations of inappropriate restraint and seclusion use and situations that may lead to patient injuries and death. There may be costs associated with developing training programs for staff regarding restraint and seclusion use and alternative interventions; however, we are not dictating how a hospital meets this requirement. Therefore, hospitals will be afforded the flexibility of deciding how to meet this requirement (for example, provide the training directly through ''in-house'' training, obtain a contractor to provide the training either at the hospital or off-site, etc.). We believe that the benefits associated with training staff far outweigh the costs involved since proper training will protect the hospital from situations of inappropriate restraint and seclusion use and situations that may lead to patient injuries and death.

Finally, hospitals will have to report to HCFA, through the appropriate HCFA regional office, any deaths that result from restraint or seclusion use for behavior management. We believe that the number of deaths related to restraint or seclusion use may be under reported in the United States; however, we have no concrete estimate of the number of deaths that occur per year. The *Hartford Courant*, a Connecticut newspaper, heightened public awareness of this issue with a series of articles in October 1998 citing the results of a study that identified 142 deaths from seclusion and restraint use in behavioral health treatment facilities over the past 10 years. However, this number includes deaths from seclusion and restraint use in more than just the hospital setting. There may be a small cost involved in making a telephone call to the HCFA regional offices; however, because we expect this regulation to reduce the number of deaths from restraint and seclusion use, the number of reports certainly will average less than one call per hospital per year. Therefore, we think the cost will be negligible.

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 any of the 6,163 (4,734 accredited and 1,429 nonaccredited) Medicare-participating hospitals (that is, short-term, psychiatric, rehabilitation, long-term, children's, and alcohol-drug), including small rural hospitals. Our goal is to safeguard against the mistreatment of all patients in these facilities including, but not limited to, deaths due to inappropriate seclusion and restraint use, violation of patients' privacy and confidentiality in various aspects of the health care delivery process, and systematic frustration of the patient's efforts to acquire his or her medical record. We believe the patient 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 the Patients' Rights CoP will lead to a reduction in the numbers of restraint-related injuries and deaths in hospitals.

3. Effect on Medicare and Medicaid Programs

We do not expect the implementation of the new Patients' Rights CoP to generate any significant cost to the Medicare or Medicaid programs. Also, we do not believe there will be any additional costs to the survey and certification program as compliance with this new 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 considered adding more prescriptive requirements regarding exactly where, how, when, and by whom ''notification of rights'' must be carried out. However, in the interest of flexibility and the recognition that this requirement will apply to hospitals of varying size, operating in wide ranges of localities, serving diverse populations, we did not adopt this approach. We considered very general regulations text language addressing the establishment of a hospital grievance process. However, based on public comment, we decided that to remain silent on general expectations for the grievance process could result in the absence of key ingredients that promote a meaningful, substantial process that addresses patients' concerns and promotes their rights. We believe that the establishment of a grievance process promotes patient empowerment in health care. To promote the creation of an effective grievance process, we are establishing general elements that should be common to grievance processes across all hospitals. Development of more detailed strategies and policies to comply with the requirement will be left to the discretion of each hospital.

We originally considered developing one set of very general requirements regulating restraint and seclusion use in all hospitals for all situations. However, based on public comments and recent concerns about restraint and 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 licensure and scope of practice are within a State's domain, and considering that other types of licensed independent practitioners provide a great deal of care in rural and frontier areas, we did not adopt that approach. However, we are requesting comment on whether we should adopt more restrictive requirements that would allow only physicians to order restraints or seclusion for behavior management.

Regarding the time frames in which a physician or licensed independent practitioner must see and assess a patient after initiation of restraints or seclusion for behavior management, we considered adopting the Pennsylvania Office of Mental Health policy of a ½ hour time frame. However, we recognized that this requirement might not be realistic for rural or frontier areas where it may be impossible to get a physician or licensed independent practitioner to the hospital in ½ hour. Therefore, we propose a 1 hour time frame and ask the public for comment.

We considered adopting more restrictive requirements for the maximum time frames for the length of an order for restraint and seclusion. However, since there was no supporting literature or studies, we decided to adopt the approach and time frames 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 issues of seclusion and restraints. In addition, 80 percent of the Medicare- and Medicaid-participating hospitals are already subject to these requirements. Therefore, we believe it is reasonable to adopt requirements similar to those of JCAHO.

D. Conclusion

The new Patients' Rights CoP for hospitals sets forth six standards that ensure minimum protections of each patient's physical and emotional health and safety. These standards address each patient's right to (1) Notification of his or her rights; (2) the exercise of his or her rights in regard to his or her care; (3) privacy and safety; (4) confidentiality of his or her records; (5) freedom from restraints used in the provision of acute medical and surgical care unless clinically necessary; and (6) freedom from seclusion and restraints used in behavior management unless clinically necessary. The Patients' Rights CoP is a new requirement for hospitals. Therefore, we have prepared a voluntary analysis consistent with the analysis set forth by the RFA. We solicit public comments on the extent that any of the entities would be significantly economically affected by these provisions.

VII. Collection of Information Requirements

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

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comment on each of these issues for the information collection requirements summarized and discussed below.

Section 482.13 Condition of Participation: Patients' Rights

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 patient care whenever possible.

We anticipate that a hospital will provide a single ''Notice of Patients'' Rights'' to each patient or his or her representative at the time of admission. As referenced in this regulation the disclosure notice must inform each patient of his or her right to (1) File a grievance and whom the patient can contact to file a grievance; (2) participate in the development and implementation of his or her plan of care; (3) make decisions regarding his or her care; (4) be informed of his or her status, involved in care planning and treatment, and the ability to refuse treatment; (5) 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, § 489.102, and § 489.104; (6) personal privacy; (7)

receive care in a safe setting, free from verbal or physical abuse or harassment; (8) confidentiality of his or her clinical records and the ability to access information contained in his or her clinical records within a reasonable time frame; and (9) be free from restraints and seclusion of any form used as a means of coercion, discipline, convenience, or retaliation by staff.

The burden associated with this requirement is the time and effort necessary to disclose the notice requirements referenced above to each patient. We estimate that on average it will take each of the 6,097 estimated hospitals 8 hours to develop the required notice and that it will take each hospital 5 minutes to provide each notice, with an average of 5,515 notices provided per hospital on an annual basis. Therefore, the total annual burden associated with this requirement is 2,850,801 hours.

In its resolution of the grievance, a 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.

The burden associated with this requirement is the time and effort necessary to disclose the written notice to each patient who filed a grievance. We estimate that on average it will take each hospital 15 minutes to develop and disseminate the required notice. We further estimate that 6,097 hospitals will provide 55 notices on an annual basis, a total annual burden of 83,834 hours.

Hospitals will have to report to HCFA, through the appropriate HCFA regional office, any deaths that result from restraint or seclusion use for behavior management. The burden associated with this requirement is for hospitals to notify HCFA, via telephone call, of any deaths. Based upon current data, we estimate the number of reports to average less than 10 calls on an annual basis. Therefore, this requirement is not subject to the PRA, as defined under 5 CFR 1320.3(c).

Hospitals must maintain documentation that each of the standards and related requirements referenced in this regulation have been met. While this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA, as defined in 5 CFR 1320.3(b)(2) and 1320.3(b)(3) because this requirement is considered a usual and customary business practice; is required under State or local law; and is used to satisfy accreditation requirements.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements in § 482.13. These requirements are not effective until they have been approved by OMB.

If you have any comments on any of these information collection and recordkeeping requirements, please mail the original and three copies directly to the following:

Health Care Financing Administration, Office of Information Services, Standards and Security Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: John Burke HCFA–3018–IFC.

and

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

List of Subjects in 42 CFR Part 482

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 42 CFR chapter IV, part 482 is amended as follows:

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 (42 U.S.C. 1302 and 1395hh), unless otherwise noted.

Subpart B—Administration

2. Section 482.13 is added to subpart B to read as follows:

§ 482.13 Condition of participation: Patients' 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 Peer Review 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 recordkeeping system permits.

(e) *Standard: Restraint for acute medical and surgical care.* (1) 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. 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. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition.

(2) 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.

(3) The use of a restraint must be—

(i) Selected only when other less restrictive measures have been found to be ineffective to protect the patient or others from harm;

(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order a restraint. This order must—

(A) Never be written as a standing or on an as needed basis (that is, PRN); and

(B) 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;

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

(iv) Implemented in the least restrictive manner possible;

(v) In accordance with safe and appropriate restraining techniques; and

(vi) Ended at the earliest possible time.

(4) The condition of the restrained patient must be continually assessed, monitored, and reevaluated.

(5) All staff who have direct patient contact must have ongoing education and training in the proper and safe use of restraints.

(f) *Standard: Seclusion and restraint for behavior management.* (1) 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. 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. A drug used as a restraint is a medication used to control behavior or to restrict the patient's freedom of movement and is not a standard treatment for the patient's medical or psychiatric condition. Seclusion is the involuntary confinement of a person in a room or an area where the person is physically prevented from leaving.

(2) Seclusion or a restraint can only be used in emergency situations if needed to ensure the patient's physical safety and less restrictive interventions have been determined to be ineffective.

(3) The use of a restraint or seclusion must be—

(i) Selected only when less restrictive measures have been found to be ineffective to protect the patient or others from harm;

(ii) In accordance with the order of a physician or other licensed independent practitioner permitted by the State and hospital to order seclusion or restraint. The following requirements will be superseded by existing State laws that are more restrictive:

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

(B) The treating physician must be consulted as soon as possible, if the restraint or seclusion is not ordered by the patient's treating physician.

(C) 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.

(D) 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.

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

(iv) Implemented in the least restrictive manner possible;

(v) In accordance with safe appropriate restraining techniques; and

(vi) Ended at the earliest possible time.

(4) A restraint and seclusion may not be used simultaneously unless the patient is—

(i) Continually monitored face-to-face by an assigned staff member; or

(ii) Continually monitored by staff using both video and audio equipment. This monitoring must be in close proximity the patient.

(5) The condition of the patient who is in a restraint or in seclusion must continually be assessed, monitored, and reevaluated.

(6) 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.

(7) The hospital must report to HCFA 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.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare Hospital Insurance; Program No. 93.778, Medical Assistance Program)

Dated: May 24, 1999.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Approved: June 9, 1999.

Donna E. Shalala,

Secretary.

[FR Doc. 99–16543 Filed 6–24–99; 4:29 pm]

BILLING CODE 4120–01–P