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Medicare and Medicaid Programs: Changes to the Hospital and Critical Access Hospital Conditions of Participation To Ensure Visitation Rights for All Patients

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75 FR 70831

DATE: Friday, November 19, 2010

ACTION: Final rule.

SUMMARY: This final rule will revise the Medicare conditions of participation for hospitals and critical access hospitals (CAHs) to provide visitation rights to Medicare and Medicaid patients. Specifically, Medicare- and Medicaid-participating hospitals and CAHs will be required to have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital or CAH may need to place on such rights as well as the reasons for the clinical restriction or limitation.

EFFECTIVE DATE: *Effective Date:* These regulations are effective on January 18, 2011.

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SUPPLEMENTARY INFORMATION: On April 15, 2010, the President issued a Presidential Memorandum on Hospital Visitation to the Secretary of Health and Human Services. The memorandum may be viewed on the Web at: <http://www.whitehouse.gov/the-press-office/presidential-/memorandum-/hospital-/visitation>. As part of the directives of the memorandum, the Department, through the Office of the Secretary, tasked CMS with developing proposed requirements for hospitals (including Critical Access Hospitals (CAHs)), that would address the right of a patient to choose

who may and may not visit him or her. In the memorandum, the President pointed out the plight of individuals who are denied the comfort of a loved one, whether a family member or a close friend, at their side during a time of pain or anxiety after they are admitted to a hospital. The memorandum indicated that these individuals are often denied this most basic of human needs simply because the loved ones who provide them comfort and support do not fit into a traditional concept of "family."

Section 1861(e)(1) through (9) of the Social Security Act--(1) Defines the term "hospital"; (2) lists the statutory requirements that a hospital must meet to be eligible for Medicare participation; and (3) specifies that a hospital must also meet other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the facility. Under this authority, the Secretary has established in the regulations at 42 CFR part 482 the requirements that a hospital must meet in order to participate in the Medicare program. This authority extends as well to the separate requirements that a CAH must also meet to participate in the Medicare program, established in the regulations at 42 CFR part 485. Additionally, section 1820 of the Act sets forth the conditions for designating certain hospitals as CAHs. Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. Regulations at 42 CFR 440.10(a)(3)(iii) require hospitals to meet the Medicare CoPs to receive payment under States' Medicaid programs.

While the existing hospital conditions of participation (CoPs) in our regulations at 42 CFR part 482 do not address patient visitation rights specifically, there is a specific CoP regarding the overall rights of hospital patients contained in § 482.13. We note that the existing CoPs for CAHs in our regulations do not address patient rights in any form. The hospital CoP for patient rights at § 482.13 specifically requires hospitals to--(1) Inform each patient or, when appropriate, the patient's representative (as allowed under State law) of the patient's rights; (2) ensure the patient's right to participate in the development and implementation of the plan of care; (3) ensure the patient's (or his or her representative's) right to make informed decisions about care; (4) ensure the patient's right to formulate advance [*70832] directives and have hospital staff comply with these directives (in accordance with the provisions at 42 CFR 489.102); (5) ensure the patient's right to have a family member or representative of his or her choice and his or her own physician notified promptly of admission to the hospital; (6) inform each patient whom to contact at the hospital to file a grievance; and (7) ensure that the hospital's grievance process has a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization (QIO). (Additional information regarding the Medicare beneficiary patient's right to file a grievance or a complaint with a QIO may be found at the HHS Centers for Medicare & Medicaid Services Web site: <http://www.cms.gov/QualityImprovementOrgs/>.) The hospital patient rights CoP also guarantees a patient's right to privacy; care in a safe setting; freedom from all forms of harassment and abuse; and confidentiality of patient records. In addition, this CoP contains detailed standards on the use of restraint and seclusion in the hospital, including provisions regarding the training of staff on appropriate restraint and seclusion of patients as well as a requirement for the hospital to report any and all deaths associated with the use of restraint or seclusion.

As the President noted in his memorandum to the Secretary, many States have already taken steps to ensure that a patient has the right to determine who may and may not visit him or her, regardless of whether the visitor is legally related to the patient. In addressing the President's request to ensure patient visitation rights, we focused on developing requirements to ensure that hospitals and CAHs protect and promote patient visitation rights in a manner consistent with that in which hospitals are currently required to protect and promote all patient rights under the current CoPs. Therefore, we proposed a visitation rights requirement for hospitals and CAHs as a CoP in the Medicare and Medicaid programs. In addition to addressing the President's directives regarding patient rights, we are also ensuring that all hospitals and CAHs fully inform patients (or their representatives) of this right, and that all patients are guaranteed full participation in designating who may and who may not visit them. Therefore, we solicited public comment on how to best implement this requirement. In the proposed rule we noted that, at a minimum, the requirement should exclude a hospital or CAH from requiring documentation when the patient has the capacity to speak or otherwise communicate for himself or herself; where patient representation automatically follows from a legal relationship recognized under State law (for example, a marriage, a civil union, a domestic partnership, or a parent-child relationship); or where requiring documentation would discriminate on an impermissible basis.

In the April 15, 2010 Presidential Memorandum, the President also emphasized the consequences that restricted or limited visitation has for patients. Specifically, when a patient does not have the right to designate who may visit him or her simply because there is not a legal relationship between the patient and the visitor, physicians, nurses, and other staff caring for the patient often miss an opportunity to gain valuable patient information from those who may know the patient best with respect to the patient's medical history, conditions, medications, and allergies, particularly if the patient

has difficulties recalling or articulating, or is totally unable to recall or articulate, this vital personal information. Many times, these individuals who may know the patient best act as an intermediary for the patient, helping to communicate the patient's needs to hospital staff. We agree that restricted or limited hospital and CAH visitation can effectively eliminate these advocates for many patients, potentially to the detriment of the patient's health and safety.

An article published in 2004 in the *Journal of the American Medical Association* (Berwick, D.M. and Kotagal, M.: "Restricted visiting hours in ICUs: time to change." *JAMA*. 2004; Vol. 292, pp. 736-737) discusses the health and safety benefits of open visitation for patients, families, and intensive care unit (ICU) staff and debunks some of the myths surrounding the issue (physiologic stress for the patient; barriers to provision of care; exhaustion of family and friends) through a review of the literature and through the authors' own experiences working with hospitals that were attempting a systematic approach to liberalizing ICU visitation as part of a collaborative with the Institute for Healthcare Improvement. The authors of the article ultimately concluded that "available evidence indicates that hazards and problems regarding open visitation are generally overstated and manageable," and that such visitation policies "do not harm patients but rather may help them by providing a support system and shaping a more familiar environment" as they "engender trust in families, creating a better working relationship between hospital staff and family members."

II. Provisions of the Proposed Rule and Response to Comments

We published a proposed rule in the **Federal Register** on May 26, 2010 (75 FR 29479). In that rule, we proposed to revise the Medicare hospital and CAH CoPs to provide visitation rights to Medicare and Medicaid patients.

We provided a 60-day public comment period in which we received approximately 7,600 timely comments from individuals, advocacy organizations, legal firms, and health care facilities. Of the approximately 7,600 timely comments, more than 6,300 were versions of a form letter that all expressed the same sentiment of strong support for the proposed regulation. The remaining comments, with very few exceptions, also expressed strong support for the concept and overall goals of the proposed regulation. Summaries of the public comments are set forth below.

Hospital Visitation Rights

We proposed a visitation rights requirement for hospitals as a new standard within the patient rights CoP at § 482.13. In that provision, we specified that hospitals would be required to have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights as well as the reasons for the clinical restriction or limitation. As part of these requirements, the hospital must inform each patient, or his or her representative where appropriate, of the patient's visitation rights, including any clinical restriction or limitation on those rights, when the patient, or his or her representative where appropriate, is informed of the other rights specified in § 482.13. We also proposed that, as part of his or her visitation rights, each patient (or representative where appropriate) must be informed of his or her right, subject to his or her consent, to receive the visitors whom he or she designates, whether a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and of the right to withdraw or deny such consent at any time. We solicited public comment on the style and form that patient notices or disclosures would need to follow so that patients would be best informed of these rights.

We also proposed that hospitals would not be permitted to restrict, limit, [*70833] or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability. In addition, we proposed to require hospitals to ensure that all visitors designated by the patient (or representative where appropriate) enjoy visitation privileges that are no more restrictive than those that immediate family members would enjoy.

Visitation Rights With Respect to CAHs

We proposed to apply the same visitation requirements to CAHs by revising the CoPs for CAHs. Because the CoPs for CAHs do not contain patient rights provisions, we proposed to add a new standard on patient visitation rights at § 485.635(f) within the existing CoP on provision of services.

Comment: The vast majority of commenters expressed support for the proposed regulation. Of those commenters who submitted positive comments, many also included a rationale for their positive support. Many commenters noted the harm in keeping loved ones apart, and expressed support for the rule based on the need for compassionate treatment of all patients and loved ones. One commenter indicated it is shameful and embarrassing to ask for "special" treatment to visit a sick loved one, when it is not the hospital's decision to make in the first place. Another commenter felt there

was "no excuse" for hospitals to make such visitation decisions. One commenter stated that affording the right of an individual to choose their visitors or seek comfort is a crucial step towards challenging discrimination and improving health outcomes. A few commenters supported the proposed regulation based on the doctrine of the separation of Church (in the form of the personal religious beliefs of hospital staff) and State (in the form of official hospital policies and procedures). Other commenters supported the proposed regulation, citing the benefits that they personally experienced when their loved one was ill and they were granted access, even without having an advance directive naming them as the patient's representative. Still others described scenarios where an individual was permitted to visit a patient only because the individual lied about his or her relationship to the patient (such as claiming to be a biological relation).

Many commenters supported the rule because they believed that denying access to hospitalized loved ones is cruel and inhumane; some commenters even described such a denial as a form of punishment. The commenters expressed the sentiment that visitation is a moral issue and a basic human right, and that regardless of sexual identity or recognized marital status, one person being permitted to visit and care for another should not require a law.

Other commenters noted that some current visitation policies in facilities are discriminatory, unjust, and deny basic equal rights to some patients. Several commenters noted that facilities should be focused on providing medical treatment in keeping with the tenets of the Hippocratic oath, rather than dictating what constitutes an appropriate visitor. Commenters agreed that equal visitation rights are critical to the safety, welfare and equal treatment of persons who may unexpectedly find themselves under the care of a hospital or CAH.

Response: We thank the commenters for their support, and agree that all patients must be ensured the right to choose their own visitors. We agree that all Medicare- and Medicaid-participating hospitals and CAHs must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital or CAH may need to place on such rights as well as the reasons for the clinical restriction or limitation.

Comment: A few commenters approved of the proposed regulation, and suggested that fines, civil penalties, and/or jail time should be imposed upon hospitals and individuals that deny loved ones access to patients on an impermissible basis. Others suggested that a list of non-compliant facilities should be made available to the public.

Response: As a CoP for hospitals and CAHs, noncompliance with this provision could result in the provider's termination from the Medicare program. Medicare is the single largest health care payer in the country; therefore, being terminated from participation in the Medicare program, and therefore unable to receive Medicare payments, is a very serious consequence that all participating hospitals endeavor to avoid. Hospitals and CAHs that have been terminated from Medicare participation may also not receive Medicaid payments. Therefore, we believe that hospitals and CAHs already have a very strong incentive, absent fines and other consequences, to comply with this requirement. In addition, CMS does not have the legal authority to impose other types of sanctions for non-compliant hospitals or CAHs outside of the existing scheme. Because, at this time, no quality measures have been developed relating to compliance with this requirement, CMS is not in a position to publicly report this data. However, should a quality measure be developed in the future, this information could be included on the Hospital Compare Web site (<http://www.hospitalcompare.hhs.gov/>).

Comment: Many commenters were confused by the use of the term "representative" in this section. Commenters were unclear about whether the patient's representative for visitation purposes needed to be the patient's legal representative for decision-making purposes.

Response: We agree that using the term "representative" in this rule is confusing and may be misleading. For purposes of exercising visitation rights, we do not believe that the individual exercising the patient's visitation rights needs to be the same individual who is legally responsible for making medical decisions on the patient's behalf, though it is certainly possible for both roles to be filled by the same individual. To avoid potential confusion, we have replaced the word "representative" with the term "support person." The term "support person" will, we believe, allow for a broader interpretation of the requirement and increase flexibility for patients and providers alike. A support person could be a family member, friend, or other individual who is there to support the patient during the course of the stay. This concept is currently expressed in standard RI.01.01.01 of The Joint Commission guidelines for hospitals, and we believe that it appropriately reflects our broad interpretation of the individual who may exercise a patient's visitation rights on his or her behalf.

Comment: Commenters were uniformly supportive of the requirement for hospitals and CAHs to have written policies and procedures on visitation. Commenters were also strongly supportive of a clear, formalized, written notice proc-

ess for informing the patient and, as appropriate, would-be visitors and/or family and friends, of the patient's visitation rights. Some commenters recommended specific times as to when notice should be given, such as upon admission, as early as possible in the admissions process, and/or whenever copies of the visitation policy are requested. Other commenters suggested that the notice of visitation rights be limited to a single page. Several other commenters requested that the notice also be provided orally and in an accessible manner in accordance with Title VI of the 1964 Civil Rights Act, in order to ensure the communication of the content in an appropriate manner. Still other [*70834] commenters suggested that the notice of visitation rights should be posted in public spaces and in the patient's room.

Response: We thank the commenters for their support of the need to notify patients or their support person about their rights. We agree that hospitals and CAHs should be required to notify patients or their support person, in writing, of the patient's rights, including their right to receive visitors of their choosing. In accordance with the current requirements at β 482.13(a), Notice of rights, hospitals must inform patients or their support person, where appropriate, of the patient's rights in that hospital before care is furnished to a patient whenever possible. This requirement for providing the notice of patient rights, now including the right to designate and receive visitors, before care is initiated meets the concerns of some commenters regarding the timing of the notice. Therefore, we are retaining the current requirements of β 482.13(a) related to the timing of the notice of rights, and are finalizing the requirements of β 482.13(h)(1) and (2) specifically related to the written notice of visitation rights. Likewise, we are modifying the requirement of proposed β 485.635(f)(1) to require CAHs to notify patients of their visitation rights in advance of furnishing patient care whenever possible.

While we are finalizing the written notice of visitation rights requirement under the authority of sections 1861(e)(9) and 1820 of the Act, we agree with commenters that there are other legal requirements, most notably those under Title VI of the Civil Rights Act of 1964, that are related to this provision. Our requirement is compatible with recent guidance on Title VI of the Civil Rights Act of 1964. The Department of Health and Human Services' (HHS) guidance related to Title VI of the Civil Rights Act of 1964, "Guidance to Federal Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons" (August 8, 2003, 68 FR 47311) applies to those entities that receive Federal financial assistance from HHS, including Medicare- and Medicaid-participating hospitals and CAHs. This guidance may assist hospitals and CAHs in ensuring that patient rights information is provided in a language and manner the patient understands.

Providing each patient or support person with the written notice of visitation rights before the start of care sufficiently achieves the goal of informing patients; therefore, we are not requiring such notice to be posted within the facility. This rule does not prohibit hospitals and CAHs from posting information about their visitation policies of their own volition. Furthermore, we are not requiring facilities to provide the notice of rights in any particular format or to individuals other than the patient or support person. Facilities are already providing a notice of rights to patients in accordance with the requirements of the current rule and contemporary standards of practice. In order to facilitate prompt compliance and minimize the burden upon facilities, it is essential to allow them the flexibility to adapt their current notice procedures and documents to include this new notice of visitation rights requirement and to continue the strong focus on patients, rather than the many visitors who may pass through a facility in any given day.

Comment: In addition to notifying patients of their visitation rights, some commenters suggested that the notice should include information about any restrictions on those visitation rights, including common examples of situations when visitation may be restricted, and any specific restrictions applicable to the patient. Additionally, the following items were proposed as elements of the disclosure notice:

- . Recitation of the specific language from the regulation (that "hospitals cannot restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability");

- . Accompanying notice related to a patient's right to complete an advance directive or other designation of a health care agent to represent the patient;

- . Accompanying notice about the grievance process that a patient (or a visitor) may follow to appeal a denial of visitation; and

- . Contact information for a dedicated hospital staff person who can resolve visitation conflicts.

Response: We agree that the notice of visitation rights should include information related to reasonable, clinically necessary restrictions or limitations on those rights. Therefore, we are finalizing β 482.13(h)(1) and β 485.635(f)(1), which require hospitals and CAHs to "inform each patient (or support person, where appropriate) of his or her visitation

rights, including any clinical restriction or limitation on such rights." In order to improve compliance with this requirement and minimize the burden on providers, it is necessary to allow hospitals and CAHs flexibility in meeting this requirement. These facilities can consider the usefulness of providing examples, developing medical condition-specific notices tailored to the common needs of different patient populations, and/or reciting the text of this rule as they develop their visitation rights notice.

We also agree that hospitals should notify patients of their advance directive rights and their right to access the hospital's grievance system, and information on how to do so. This information is currently required to be provided to patients or their support person in accordance with § 482.13(a) and (b).

Comment: Several commenters suggested that CMS identify (and create, where necessary) best practices for training staff and administrators on cultural competency and the benefits of open visitation policies. Several commenters suggested that hospitals should be required to train their staff in discrimination prevention and cultural competency, to better assure that the rights of patients are promoted and protected.

Response: We thank the commenters for their suggestions. However, we believe that it is outside the scope of this rule for CMS to identify or create best practices for training various healthcare facility staff on cultural competency and the benefits of open visitation policies. We believe that the establishment of these rules will lead hospitals and CAHs to actively seek out and implement best practices and other recommendations for training staff on these issues in order to fully comply with the CoPs and continue participation in the Medicare and Medicaid programs. We encourage hospitals to address issues of cultural competencies specific to the needs of their unique patient populations as part of their quality assessment and performance improvement programs. In the future, CMS may use subregulatory guidance and technical assistance programs (such as Medicare Learning Network at <http://www.cms.gov/MLNGenInfo/>) to make known best practice information that is developed by other entities and organizations.

Comment: Several commenters suggested that complaints regarding the patient's visitation rights should be subject to a grievance process, and that the right to file a grievance should be readily available to the patient as well as any would-be visitor.

Response: If a patient believes that his or her visitation rights have been violated, the patient or his or her representative may file a grievance with the hospital using the hospital's internal grievance resolution process. We note that CAHs are not currently required to have an internal complaint process; [*70835] nonetheless, they may have such a process in place for quality improvement, State licensure, accreditation, or other reasons. If the patient believes that the quality of their care was negatively impacted by a violation of his or her rights, the patient may also file a complaint with the State survey agency responsible for oversight of the facility, or the body responsible for accrediting the facility (if applicable). In the case of Medicare beneficiaries, complaints may also be filed with the QIO in that State. These external complaint processes are available to both hospital and CAH patients. We believe that these current complaint resolution mechanisms offer the necessary protections for patients who believe that their rights have been violated. Likewise, if a visitor believes that a hospital or CAH is not complying with the requirements of this rule, the visitor may file a complaint with the State survey agency responsible for oversight of the facility, as well as the body responsible for accrediting the facility (if applicable).

Comment: A few commenters requested examples of how the new regulation will be implemented in facilities.

Response: This final rule requires hospitals and CAHs to notify a patient or support person of his or her visitation rights, and sets forth the need for all hospitals and CAHs to establish non-discriminatory visitation policies that treat all visitors equally, consistent with the designations of patients or support persons. This applies to all patients, regardless of their payment source. These are broad expectations and rights that afford facilities the flexibility to revise current practices and procedures as necessary to meet these expectations. As such, we are not in a position to provide specific examples of how the regulation will be implemented in any facility because we do not know the particular circumstances of each facility, their current policies and practices, their particular patient populations, etc.

Comment: Several commenters suggested additional protected categories that should be added so that hospitals and CAHs are explicitly prohibited in regulation from discriminating against additional specified populations. Commenters stated that the protected categories in the proposed rule should be expanded to also include: marital status, family composition, age, primary language and immigration status. In addition, commenters suggested that the proposed rule make explicit that institutional or individual conscience cannot be used to deny a visitor access to the patient.

Response: As revised, we believe that this rule makes clear that hospitals must establish and implement visitation policies that grant full and equal visitation access to all individuals designated by the patient or support person, consis-

tent with patient preferences. Patients (or their support persons) may designate anyone as an approved visitor, and a hospital or CAH may not discriminate against any approved visitors (and may impose only reasonable, clinically necessary restrictions or limitations on visitation). We believe that this regulatory policy is responsive to the concerns of commenters while still adhering to the specific instructions of the President's April 15, 2010 memorandum to the Secretary. Therefore, we are not expanding the list of explicitly protected classes at this time.

Comment: Several commenters stated that they feared crossing state lines because not all States recognize the legal status of relationships in the same way. Without such consistent recognition of legal status, an individual may be recognized as the default decision making authority by one State, but may not be recognized as such by another State. A few commenters also stated that, while traveling, it could be difficult to obtain the documentation required to verify the legal status of a relationship, particularly in emergency situations. Commenters noted that, even if documentation of a legal relationship as recognized in a certain State was available while traveling and medical attention was needed, people may not seek treatment because they fear that their legal relationship documentation may not be recognized by the State in which they are traveling.

Response: We understand the concerns of commenters in this area. These concerns highlight the need for individuals to establish an advance directive as described in 42 CFR Part 489. As a legal document expressing the patient's preferences in one or more areas related to medical treatment, an advance directive can designate the individual who is permitted to represent the patient, should the patient become incapacitated. Although section 1866(f)(1) of the Act defers to State law (whether statutory or established by the courts) to govern the establishment and recognition of advance directives, we believe that this type of document continues to be a generally viable option for patients seeking to document, in writing, their representative and/or support person designation and treatment preferences. Consistent with provisions concerning the establishment and recognition of advance directives, all States continue to have the right to determine the legal relationships that will be recognized by State law and practice, to the extent that they do so in accordance with constitutional principles. We do not have the authority in this rule to compel one State to recognize a legal relationship that is established in another State. That said, we remind hospitals and CAHs that this rule does require full and equal visitation for all visitors who are designated by the patient or support person, consistent with the patient's preferences. It is our understanding that, even where one State does not recognize a legal relationship recognized by another State, the law of that State generally does not prohibit a private actor in that State--such as a hospital or CAH--from recognizing that legal relationship. Thus, there generally appear to be no barriers to such a hospital or CAH recognizing a legal relationship recognized by another State, even if its own State does not recognize that legal relationship.

Comment: A few commenters expressed concern that the validity of an adoption in one State may not be recognized by another State in cases where a minor is the patient. Commenters feared being required to verify proof of parenthood at the height of a medical emergency if located in a different state than where adoption occurred. Concern about the minor patient's representative having the right to make decisions about medical care "as allowed under State law" was also noted by few commenters. Commenters felt that, as the language in the regulation stands, it may allow hospitals to deny the ability of adoptive parents to act as a minor patient's representative, even though the adoptive relationship is recognized under the laws of a different State. Other commenters expressed concern about the ability of non-biological parents to make decisions for their child in the absence of a legal adoption. Commenters expressed these same concerns with respect to the ability to visit a minor child.

Response: A legal adoption in one State is generally recognized as a legal parent-child relationship in another State, along with all of the default decision-making authorities that such a legal relationship confers upon a legal parent. This legal relationship continues to exist even if that parent and minor crosses State lines into another State in which that parent would have been prohibited from adopting that child. As a legal parent and representative of the minor child, the legal parent is, in accordance with the requirements of [*70836] this final rule, able to designate those individuals who are permitted to visit the child. Thus, this rule ensures the representative's ability to ensure visitation access for other individuals.

Under this rule, issues of non-biological and non-adoptive parents acting as the minor child's decision maker are governed by State law. While we do not have the authority in this final rule to compel a State to generally recognize such parents as legal parents, we note that some States in fact recognize "de facto" or "functional" or "equitable" parenthood, *i.e.*, recognize non-biological and non-adoptive parents as legal parents. Nothing in this rule prohibits a hospital or CAH from recognizing non-biological and non-adoptive parents as legal parents for purposes of the visitation policies set forth in this rule.

Comment: Several commenters stated that they supported the proposed visitation regulation because it is critical for patients to be able to choose their own visitors, particularly for those patients who belong to blended families. Commenters described "families of choice"--strong relationships with friends and other people who support the patient and who can be contacted during times of need. Accordingly, commenters stated that, when a patient is incapacitated, the patient's representative (which we now refer to as a support person) should not be chosen solely based on an individual's legal relationship with the patient. Commenters noted the lack of protection for "families of choice," which do not necessarily fit a traditional definition of a family, one based on bloodlines, marriage, or adoption, make it difficult for visitors to gain access to sick loved ones. Commenters noted that these representatives and sources of support should enjoy full visitation rights as any biological family member of the patient would.

Response: We appreciate the support of commenters, as it confirms our understanding that this visitation rights rule will help ensure that patients have access to their chosen loved ones while the patient is being cared for in a hospital or CAH. We also agree that oral designation of a support person, regardless of a particular relationship's legal status, should be sufficient for establishing the individual who may exercise the patient's visitation rights on his or her behalf, should the patient be unable to do so. In the absence of a verbal support person designation, hospitals and CAHs would look to their established policies and procedures for establishing a support person for the purpose of exercising a patient's visitation rights. As discussed later in this section, there are numerous sources of information and documentation that may be appropriate to establish the appropriateness of an individual to exercise an incapacitated patient's visitation rights on his or her behalf. We note that this section does not apply to designation of an individual as the patient's representative for purposes of medical decision making, as this designation may be governed by State law and regulation.

Comment: Many commenters submitted personal anecdotes related to their hospital and CAH visitation experiences. Some stated that they were denied information about or access to a sick loved one while in the hospital. In contrast, some commenters requested examples of situations where patient visitation rights have been violated. Other commenters noted that if they were to be hospitalized in the future, they would like for their spouse or domestic partner to be able to make medical decisions on their behalf. Several commenters stated that they had prepared advance directive documentation in the event something should warrant a hospital visit for themselves and/or a spouse or domestic partner, while others expressed concern about advance directives, stating that they cannot rely on those directives being honored in all health care settings, institutions, or States uniformly, based on their marital/relationship status. Still other commenters appeared to believe that this final rule removes the need for advance directives to designate healthcare decision makers.

Response: We appreciate all of the experiences and concerns shared by the commenters, and we encourage those commenters who sought examples of patient visitation rights being denied to refer to the many detailed personal examples that were submitted to us (*see* <http://www.regulations.gov>. In the "key word or I.D." entry field, enter the docket ID (CMS-2010-0207). Then, select "public submissions" from the drop-down menu under "select document type"). Numerous comments reaffirmed our understanding of the current practice in some medical institutions that denies patients access to their loved ones in times of need. The commenters also confirmed our understanding of the public's deeply-held desire to be with loved ones in such medical institutions, which further validates the need for this final rule. We also appreciate the comments related to advance directives, and encourage individuals to establish written advance directives that document the selection of a designated patient representative, support person, and/or the patient's choices about specific medical conditions and treatments. We believe that such documentation will help ensure that the patient's wishes are honored. We acknowledge that the Act defers to State law to govern advance directive issues, and that such deference may be a source of concern to commenters. However these advance directive issues are beyond the purview of this rule.

Comment: We received numerous comments affirming our general position that, when a patient can speak for himself or herself, a hospital or CAH does not need to require written documentation of a patient representative. That is, the commenters supported our contention that oral designation of "representative" status is sufficient. Comments also suggested that no proof should be required in cases where the patient provides oral confirmation that he or she would like to receive any particular visitor. Furthermore, the commenters advocated against a formal documentation process, whereby the hospital would be asked to obtain a list of permitted and non-permitted visitors from each patient. They stated that, as a practical matter, it would be simpler for the hospital to recognize as welcome or not any particular potential visitor, per the patient's wishes, when that patient make his or her wishes known.

Response: We agree that an oral designation of a support person (formerly known as a "representative") is sufficient for establishing the individual who may exercise the patient's visitation rights on his or her behalf, should the patient be unable to do so. We also agree that the patient's or support person's oral consent to admit a visitor or to deny a

visitor is sufficient evidence of their wishes, and that further proof of those wishes should not be required. However, hospitals and CAHs are permitted to record such information in the patient's record for future reference, if they so choose.

Comment: Some commenters submitted comments related to the rare cases in which hospitals may need to require written documentation of patient representation. Of these, some commenters suggested that documentation should be required only in cases where more than one person claims to be the patient's spouse, domestic partner or surrogate. Others suggested that proof should be required only if the patient is incapacitated. Other commenters suggested dropping "proof" requirements altogether in an emergency situation and/or if the [*70837] patient is unconscious or otherwise incapacitated. A few commenters stated that the visitor should not have to leave the bedside of the patient to obtain proper documentation, while others stated that proof should not be required of same-sex couples where it is not required of similarly-situated different-sex couples. Other comments to this effect went further, suggesting that hospitals requiring documentation from a same-sex couple but not a different-sex couple in the same situation would be engaging in discrimination on an impermissible basis (*i.e.* on the basis of sexual orientation).

Response: We agree with those commenters who stated that a hospital or CAH must apply its documentation policy equally for all patients and support persons. In accordance with the comments submitted with respect to this rule, we believe that documentation to establish support person status for the purpose of exercising a patient's visitation rights should be required only in the event that the patient is incapacitated and two or more individuals claim to be the patient's support person. Since the visitation rights provision is new, we do not believe that States have established separate laws and regulations that would require documentation to establish an individual as the support person in other circumstances. While we acknowledge the desire of the individuals who claim to be the patient's support person to remain at the patient's bedside, we recognize that this is not possible in every situation. In these situations, such individuals may need to leave the area in order to obtain written documentation of the patient's wishes. Individuals may wish to maintain such documentation on their person and/or maintain such documentation in an electronic database, such as an advance directive registry, that grants access to health care facilities in order to avoid leaving the patient's bedside to obtain proof of support person status.

Comment: A few comments spoke to matters beyond a support person's ability to visit and designate other visitors, suggesting that, where the patient is unable to communicate and decisions related to providing or withdrawing medical care are necessary, documentation should be required, unless the patient designated the representative for health care decision making before being unable to communicate.

Response: We agree that situations related to medical decision making are governed by State law, whether established under legislative or judicial authority. We note that issues of surrogate medical decision making fall outside the scope of this rule on visitation policies. Hospitals and CAHs must always comply with their State laws and regulations, and we remind facilities that their policies and procedures related to requiring documentation of support person status must be applied in a non-discriminatory manner.

Comment: Comments were received regarding what forms of proof might suffice to establish the appropriateness of a visitor where the patient is incapacitated or otherwise unable to designate visitors, and a representative in accordance with State law or a patient-designated support person is not available to exercise the patient's rights on his or her behalf. Comments also suggested that these forms of "proof" could also be used to help establish a support person's status as such.

The following forms of "proof" were suggested:

- . An advance directive naming the individual as a support person, approved visitor or designated decision maker (regardless of the State in which the directive is established);

- . Shared residence;

- . Shared ownership of a property or business;

- . Financial interdependence;

- . Marital/Relationship status;

- . Existence of a legal relationship recognized in another jurisdiction, even if not recognized in another jurisdiction, including: Parent-child, civil union, marriage, domestic partnership;

- . Acknowledgment of a committed relationship (e.g. an affidavit); and
- . Written documentation of the patient's chosen individual(s) even if it is not a legally recognized advance directive.

Response: We agree that any of these forms of proof could be sufficient for hospitals and CAHs to establish the appropriateness of a visitor when a patient is incapacitated and no representative or support person is available to exercise a patient's visitation rights on his or her behalf. We also agree that these forms of proof may be helpful for establishing support person status for the purpose of exercising the patient's visitation rights when the patient is incapacitated. In order to obtain this information, hospitals and CAHs may choose to examine licenses, State identification cards, bank statements, deeds, lease agreements, etc. These lists of proof and documentation are not intended to be exhaustive of all potential sources of information regarding patient visitation or support person preferences. Our overall expectation is that hospitals and CAHs will use this information to guide the establishment of flexible policies and procedures that balance the dual needs of ensuring patient safety and ensuring patient access to loved ones.

Comment: A few commenters suggested that the final rule should ensure that patients have the right to exclude certain visitors to assure their well-being, and that the patient's support person should have the highest level of authority to do so.

Response: We agree that the patient's right to choose visitors also includes the right to deny visitors. We included this concept at proposed β 482.13(h)(2) and β 485.635(f)(2), stating, "Inform each patient (or representative, where appropriate) of his or her visitation rights * * * and his or her right to withdraw or deny such consent at any time." We continue to believe that this is an appropriate provision and are finalizing it as such. Patients, or their support person acting on their behalf, have the right to deny visitors.

Comment: Some commenters suggested that the regulation should include an explicit requirement granting the patient's support person direct access to the patient. One commenter suggested that health care proxies or powers of attorney that are legally recognized in one State also be recognized by hospitals and CAHs in other States for the purpose of establishing visitation rights.

Response: We agree that the patient's representative and/or support person, as the individual responsible for exercising the patient's rights on the patient's behalf when the patient is incapacitated or otherwise unable to do so directly, should be granted direct access to the patient. This basic concept is embodied throughout the current hospital regulations, including through the requirement at β 482.13(a) and (b) that the patient or patient's representative must be informed of the patient's rights and how to exercise those rights. We also agree that using the information provided in an advance directive or other written document, whether it is or is not legally recognized by the State, may be useful for hospitals and CAHs when trying to determine appropriate visitors when a patient is unable to communicate his or her own wishes and a legal representative as established consistent with State law or a support person is not available to exercise the patient's visitation rights on his or her behalf.

Comment: A number of commenters expressed the concern that the regulation's reference to State law, as it pertains to the hospital's recognition of [*70838] a patient's representative, could be interpreted as inappropriately limiting the designation of a representative, and suggested that we remove "as allowed under State law" from the regulation.

Response: As previously discussed, we agree that using the term "representative," with its implicit links to state law, is too narrow for this regulation. Therefore, we have replaced the term "representative" with the term "support person," which is intended to broadly describe the family member, friend, or other individual who supports the patient during his or her hospital or CAH stay and may exercise the patient's visitation rights on his or her behalf. Issues of legal representation and health care decision making are beyond the purview of this final rule. We remind all hospitals and CAHs that these issues are generally addressed in State law (including case law). All Medicare-participating providers, including hospitals and CAHs, are required to remain in full compliance with the laws and regulations of their State, in addition to these Federal requirements.

Comment: A few commenters noted that they were denied access to visit a loved one by the patient's representative, although they believed that such a denial was not in the best interest of the patient. The commenters cited their ability to provide pertinent medical information about the patient as a primary reason for allowing them access to the patient despite the decision of the patient's representative. A few comments also noted the impact of the well-recognized legal concept of "substituted judgment" as requiring patients' families and representatives to make medical decisions based on the patient's values and interests and not their own.

Response: As the individual responsible for making decisions on the patient's behalf, the patient representative has the authority to exercise a patient's right to designate and deny visitors just as the patient would if he or she were capable of doing so. The designation of and exercise of authority by the patient's representative is governed by State law, including statutory and case law. Many State courts have addressed the concept of substituted judgment, whereby the patient representative is expected to make medical decisions based on the patient's values and interests, rather than the representative's own values and interests. State courts have also developed a body of closely related law around the matter of a representative acting in the patient's best interest. Such case law regarding substituted judgment and best interest may be a resource for hospitals and CAHs as they establish policies and procedures intended to address these difficult situations. Hospitals and CAHs may also choose to utilize their own social work and pastoral counseling resources to resolve such conflicts to assure the patient's well-being.

Comment: Some commenters suggested that we replace the term "immediate family," as proposed at β 482.13(h)(4) and β 485.635(f)(4), with a broader requirement that does not distinguish among different types of relationships. Some commenters asserted that the regulation, as proposed, would be difficult to define, measure, and enforce. Furthermore, some commenters stated that the regulation, as proposed, created the appearance of a hierarchy of family relationship status that could put other chosen family members and loved ones at risk of unequal treatment.

Response: We agree that the proposed language may have been difficult to define, measure, and enforce, and that amending the requirement would further clarify our intent to assure equal visitation privileges for all visitors in accordance with the patient's preferences. Therefore, we have amended the requirements at β 482.13(h)(4) and β 485.635(f)(4) to state, "Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences." This revised requirement is patient-centered and will, we believe, ensure that all visitors are treated in a fair and equal manner by a hospital or CAH.

Comment: Many commenters suggested that we broaden the context in which the word "family" is used. Commenters presented a variety of options, citing sources such as the Joint Commission, the Office of Personnel Management for the United States government, and current practices in New York State. All of these commenters suggested a broad concept of family, including any individual who plays a significant role in the patient's life, such as spouses, domestic partners, significant others (whether different-sex or same-sex), and other individuals not legally related to the patient. Commenters also provided a list of specific types of family relationships, and described the challenges that can be faced with respect to each.

Response: We believe that both the preamble to the proposed rule and the language of the proposed requirements broaden the definition of "family" in the context of hospital and CAH visitation rights of patients. The language of the proposed rule (*See* 75 FR 36612) provides examples of visitors very similar to those given by the commenters ("a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend"). Most importantly, the proposed requirements go beyond these examples by specifying that the patient has the right to designate all visitors, regardless of type of relationship, and, while patient-designated visitors may obviously include those mentioned, the requirements do not place limits on who may be designated as a visitor by the patient. This final rule maintains the policies articulated in the proposed rule in this regard.

Comment: Commenters from the provider community expressed broad support for the rule's recognition of the need for clinically necessary or reasonable restrictions or limitations on visitation. In addition to supporting the overall concept of "necessary restrictions," some commenters stated that restrictions must be enforced uniformly and restrictions must be clearly communicated, along with their medical basis, to would-be visitors and/or the patient. These commenters stressed that such additional measures would reduce the opportunity for discrimination and increase understanding. These comments reflect the concerns of some commenters that an allowance for "reasonable" restrictions would be too broad. There were concerns among some of the commenters that a hospital or CAH might apply this exception capriciously and without adequate clinical justification, and that such a broad exception might also allow for restrictions rooted in discriminatory attitudes toward lesbian, gay, bisexual, and transgender people or their families.

Several commenters asked for clarification on the language in the proposed regulation that would allow for a hospital or CAH to place limitations or restrictions on a patient's visitation rights when it determined that it was clinically reasonable or necessary to do so. A commenter requested that one of the examples of a clinically reasonable restriction on visitation, which was used in the preamble ("when the patient is undergoing care interventions"), be stricken entirely from this rule. This commenter was concerned that a hospital or CAH might apply this example too broadly when restricting visitation for a patient, and that the reasons for applying it might be more logistical than clinical (*e.g.*, it may be used by overworked staff to justify a restriction or limitation).

The commenters provided numerous examples of legitimate reasons for [*70839] restricting or limiting visitors, including:

- . Any court order limiting or restraining contact;
- . Behavior presenting a direct risk or threat to the patient, hospital staff, or others in the immediate environment;
- . Behavior disruptive of the functioning of the patient care unit;
- . Reasonable limitations on the number of visitors at any one time;
- . Patient's risk of infection by the visitor;
- . Visitor's risk of infection by the patient;
- . Extraordinary protections because of a pandemic or infectious disease outbreak;
- . Substance abuse treatment protocols requiring restricted visitation;
- . Patient's need for privacy or rest;
- . Need for privacy or rest by another individual in the patient's shared room.

Response: We appreciate the support of commenters for this provision of the proposed rule, and agree that this list, though not exhaustive, is an appropriate way to begin considering clinically appropriate restrictions on visitation privileges.

In his April 15, 2010 memorandum on hospital visitation rights, the President directed the Secretary to initiate appropriate rulemaking that "should take into account the need for hospitals to restrict visitation in medically appropriate circumstances as well as the clinical decisions that medical professionals make about a patient's care or treatment." In crafting the language of the requirements, we took this Presidential directive into account, and thoroughly weighed the rights of a patient to receive visitors of his or her choosing against the obligation and duty of a hospital or CAH to provide the best possible care to all of its patients. We firmly believe that the requirements must allow hospitals and CAHs some flexibility regarding patient visitation so that healthcare professionals may exercise their best clinical judgment when determining when visitation is, and is not, appropriate. We believe that the best clinical judgment takes into account all aspects of patient health and safety, including any negative impact that patients, visitors, and staff may have on other patients in the hospital or CAH.

In the preamble to the proposed rule, we provided three broad examples of clinically reasonable areas where hospitals and CAHs might impose restrictions or limitations on visitors: When the patient is undergoing care interventions; when there may be infection control issues; and when visitation may interfere with the care of other patients. There are other, similarly obvious areas where restriction or limitation of visitation would also be appropriate, and which commenters also pointed out: Existing court orders restricting contact of which the hospital or CAH is aware; disruptive, threatening, or violent behavior of any kind; patient need for rest or privacy; limitations on the number of visitors during a specific period of time; minimum age requirements for child visitors; and inpatient substance abuse treatment programs that have protocols limiting visitation. While all of these instances can be discussed individually, it may be more useful to group all of these examples, plus those examples that we mentioned in the preamble, under an even broader category of clinically appropriate and reasonable restriction or limitation on visitation: When visitation would interfere with the care of the patient and/or the care of other patients. Whether the reason for limiting or restricting visitation is infection control, disruptive behavior of visitors, or patient or roommate need for rest or privacy, all of these reasons may be considered as clinically reasonable and necessary when viewed in light of a hospital's or CAH's overarching goal of advancing the care, safety, and well-being of all of its patients. As we discussed in the preamble, we believe that current clinical thinking, along with some evidence in this area, supports the role of visitation in advancing the care, safety, and well-being of patients. However, we must caution commenters that visitation is but one aspect of patient care. Hospitals and CAHs must balance all aspects of care for all patients. Through the hospital and CAH CoPs, CMS expects all hospitals and CAHs to provide care to patients in a safe manner that follows nationally recognized guidelines and standards. As part of this expectation, CMS recognizes that hospitals and CAHs must be allowed some degree of flexibility when developing policies and procedures for patient care and safety, and in order to comply with the CoPs. We remind hospitals and CAHs that, when establishing and implementing visitation policies and procedures, the burden of proof is upon the hospital or CAH to demonstrate that the visitation restriction is necessary to provide safe care.

As it is written, the requirement does allow a hospital or CAH a degree of flexibility when developing and imposing policies that may limit or restrict visitation. However, the rule does require that a hospital or CAH must contain these policies in written form, including the reasons for such restrictions, and must inform a patient (or his or her support person) of its policies regarding clinical limitations or restrictions on visitation rights.

However, while we agree that a hospital or CAH must communicate its policy on limited or restricted visitation to patients when apprising them of their rights (and the requirement is written as such), we do not believe that a hospital or CAH must delineate each of the clinical reasons that may warrant imposition of this policy because it may be impossible to anticipate every instance that may give rise to such a situation. We do believe that hospitals and CAHs should clearly communicate how such policies are aimed at protecting the health and safety of all patients. Additionally, in situations where it may be necessary for patient visitation to be limited or restricted, hospitals and CAHs have a duty to the patient to clearly explain the reasons for such restrictions or limitations.

Further, we disagree that the example given in the preamble of a clinically reasonable or necessary restriction or limitation on visitation ("when the patient is undergoing care interventions") should be stricken from the rule entirely. This language was not included in the proposed requirements nor is it being finalized here; it was used merely as an example. However, we are aware that in some hospitals and CAHs throughout the nation, there still exists an unwritten policy of "clearing the room" of all visitors when a patient is undergoing an intervention. It should be noted here that there are often valid reasons for doing this. For instance, many patients prefer privacy during this time; many visitors are not prepared to witness the physical aspects of some patient care interventions and procedures; the physical limitations of the patient's room can make the intervention difficult to perform with visitors in the room; and, when performing interventions or procedures that require aseptic technique, additional persons or visitors in the room may compromise the healthcare professional's ability to control for infection. CMS believes that it is in the patient's best interest to allow those healthcare professionals responsible for the care of the patient to make these clinical decisions regarding restricting or limiting visitation when the patient is undergoing a procedure or intervention.

However, we must emphasize here that we strongly encourage hospitals and CAHs to be aware of, and sensitive to, the needs of any patient who may request that at least one visitor be allowed to stay in the room to provide [*70840] support and comfort when undergoing a procedure, and to make a best effort at accommodating such requests if the clinical situation allows for it. Despite the hospital culture of "clearing the room" for patient care interventions that may still exist in some hospitals and CAHs, we believe that many more hospitals and CAHs are making a best effort at recognizing and honoring the need of many patients to have a loved one close by while undergoing a potentially frightening and painful procedure. In this regard, we respectfully disagree with the comment stating that staff may justify such restrictions or limitations for logistical, rather than clinical, reasons. This comment voices a concern that "overworked staff" would apply restrictions or limitations for logistical reasons and implies that logistical reasons are more conveniences for the staff than they are clinical reasons for the patient. In the hospital setting, the logistical and the clinical are often one and the same, and the logistics of the situation must sometimes be taken into account by healthcare professionals in order to ensure the best clinical outcomes for patients. Of the examples given above for restricting or limiting visitation during a care intervention, it can be argued that all are both clinical and logistical in nature, with each impacting the other. Again, CMS believes that, in the interests of patient safety, such decisions are best left to the healthcare professionals responsible for the care of the patient, and should not be dictated through overly prescriptive regulations.

Comment: Several commenters stated that written documentation of patient representation in the form of legally valid advance directives, such as durable powers of attorney and healthcare proxies, (as opposed to oral designation of the support person by the patient) should be required only in the very rarest of cases--such as when more than one person claims to be a patient's spouse, domestic partner, or surrogate. In all other cases, oral confirmation of an individual acting as the support person should suffice. Commenters suggested that a hospital or CAH may not require documentation in a discriminatory manner.

Response: In the preamble, we specifically asked for comments on how to best identify those rare cases where hospitals and CAHs should be permitted to ask for written documentation to establish the support person as such in order to allow the support person the right to designate visitors if the patient is unable to do so. We appreciate the comments offered on this issue. We agree that this practice would most clearly be justified in those rare cases where the hospital or CAH faces a dispute among two or more persons claiming to be the patient's support person, and the patient is incapacitated.

Comment: One provider urged CMS to be cautious about fashioning "overly prescriptive" policies in the interpretive guidelines.

Response: We appreciate the commenter's warning, and agree that being overly prescriptive may stifle the flexibility that we intend hospitals and CAHs to exercise when establishing and implementing full and equal visitation for all visitors in accordance with patient preferences. We note that the Interpretive Guidelines for the CoPs, which will be updated to reflect these new requirements, fall outside of the scope of this rulemaking process and are not addressed here.

Comment: A very small number of commenters suggested that CMS should not adopt this proposed rule, believing that there does not exist a pressing need for it to exist, and that adding the additional patient rights information to the existing notice of patient rights disclosure would serve only to increase hospital costs, lengthen the admission process, and further overwhelm patients.

Response: While we recognize the commenters' concern regarding the large amount of information that is provided to patients and the time that it takes to do so, we continue to believe that it is better to apprise patients and their support person of the patient's rights, and to ensure this practice through the requirements of the conditions of participation. We also continue to believe that this regulation will address a very real problem that negatively impacts patient outcomes and that runs contrary to our goal of safe and effective care for every patient, every time. Furthermore, we continue to believe that the flexible structure of these requirements minimizes the cost impact of this final rule.

Comment: Several commenters made ambiguous statements that did not speak to either support for or disagreement with the proposed rule.

Response: While we believe that statements such as "Please come into the new millennium" may be in support of the proposed regulation, encouraging CMS to adopt regulations that address changing social norms and contemporary situations, we were unable to classify these comments as such due to their ambiguous nature. Nonetheless, we thank the commenters for expressing their thoughts on this proposed regulation and will make all efforts to assure that the final regulation is fair and balanced to protect patient rights, as well as patient health and safety.

Comment: Several commenters in favor of the regulation proposed that all hospitals, whether they are receiving Federal funding from CMS or not, respect this directive and its intention.

Response: While we agree that the intent and spirit of this regulation should be honored by all hospitals and CAHs, even those that do not receive Medicare or Medicaid funds, we do not have the authority to enforce these requirements upon non-Medicare or Medicaid hospitals and CAHs. CMS's authority to enforce this and other CMS regulations stems from the agreement that hospitals and CAHs enter into with CMS whereby those hospitals and CAHs agree to abide by Medicare's regulations in exchange for their ability to participate in the Medicare and Medicaid programs, see and treat Medicare and Medicaid patients, and be paid by Medicare or Medicaid for the care and services furnished to those Medicare and Medicaid patients. Absent that voluntary agreement, CMS lacks authority to enforce its rules upon non-participating providers and suppliers.

Comment: Several commenters suggested that the requirements of this rule should apply to hospices, nursing homes, ambulatory surgical centers (ASCs), and intermediate care facilities for the mentally disabled (ICF/MRs). Commenters noted that the need for and the benefits that flow from visitation are just as important--and sometimes even more so--for patients in hospices and nursing homes than for those in hospitals. Many commenters asserted that the standards and rules for all facilities should be consistent.

Response: While we agree that the benefits of visitation go beyond hospital and CAH patients, and we appreciate the suggestions that this rule should apply to other types of Medicare and Medicaid providers, such revisions would fall outside the scope of this rule. We note that the current regulations for hospices (β 418.52, β 418.100, and β 418.110 in particular) and nursing homes (β 483.10(j)) already require generous visitation privileges for all patients, and that these generous allowances minimize the need for new regulations at this time. We also believe that the short-term nature of ASC services, which must be less than 24 hours in duration, and the fact surgery centers generally require each patient to be accompanied by a responsible adult for discharge purposes, naturally minimize the need for open visitation regulations in ASCs. However, we will [*70841] continue to consider modifying the requirements for these provider types in the future to ensure consistent requirements and patient rights across providers.

Each of these providers is required by regulation to have an internal system to handle patient grievances. If patients of these providers believe that their rights have been violated, they may file a complaint using their provider's internal grievance system. All patients may also file a complaint with the state survey agency and/or the agency that accredits the provider (if applicable). Furthermore, Medicare beneficiaries may file quality of care complaints with the QIO in

that state. We believe that these robust complaint options help assure that patient complaints are documented, investigated, and resolved in an appropriate manner.

Informed Decisions

The President's Memorandum also directed the Secretary to ensure that patients' representatives have the right to make informed decisions regarding patients' care.

The hospital CoPs at 42 CFR 482.13(b)(2) state: "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."

We believe that the ability of a patient to designate a support person who can act on behalf of the patient is critical to the assurance of the patient's health and safety. Regardless of whether a patient is incapacitated, the designation of a support person, who is likely to be especially familiar with the patient, including his or her medical history, conditions, medications, and allergies, can serve as an invaluable asset to the patient and caregivers during the development and revision of the course of treatment and associated decision making.

In the proposed rule, we explained that the requirement at β 482.13(b)(2) was intended to ensure the patient's right to designate a representative for health care decision-making purposes. We solicited public comment on whether, as a health and safety measure, this requirement effectively addresses any inappropriate barriers to a patient's ability to designate a representative for visitation purposes, and consistently ensures the right to designate a representative (for all purposes) for all patients in all Medicare- and Medicaid-participating hospitals.

Comment: Several commenters noted suggestions to ensure that all patients are able to designate a decision-maker, have that designation respected, and receive meaningful representation by that individual regardless of whether the State in which the patient is hospitalized recognizes a formal legal relationship between the two persons. This would include hospitals' obligations to provide patients with designation forms. In urgent situations, commenters suggested that patients have the right to orally designate a representative for decision-making purposes. One commenter suggested that CMS should create a model advance directive rule that States could use to revise their current legislation and regulations related to advance directives.

Response: We thank commenters for their suggestions regarding the designation of a representative by a patient. With respect to designations in advance directives, β 1866(f)(1) of the Act defers to State law (whether statutory or established by the courts) to govern the establishment and recognition of advance directives (which can be used by the patient to designate a representative). Thus, we do not have the authority in this rule to change this aspect of advance directives policy. We believe, however, that an advance directive remains a viable and important option for those seeking to document treatment preferences, informed decision-making regarding care, designation of a representative, and designation of a support person (who may be the representative). And we encourage hospitals to consider advance directives established in other States as a viable source of information about patient preferences, including visitation preferences. It is not within the scope of this regulation to draft sample legislation that could guide State laws and regulations on advance directives.

Comment: Commenters expressed various concerns related to the current requirements for the establishment and implementation of advance directives, State requirements for designating a patient's representative for decision-making purposes, methods for producing a copy of an existing advance directive in a time of need (including the hospital's role in obtaining a copy), and the practicalities involved with establishing advance directives. These commenters highlighted the complexities of establishing, accessing, and implementing advance directives in a variety of circumstances, and focused particular attention on the role of advance directives in establishing patient "representative" status.

Response: We appreciate the comments received in regard to advance directive issues. We refer readers to the statutory language at β 1866(f)(3) of the Act, which defines an advance directive as "a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State) and relating to the provision of such care when the individual is incapacitated." All CMS regulations related to advance directives, including those advance directives that designate a patient's representative for health care decision making, are based on this statute which, in turn, defers to State laws in all forms to govern the es-

establishment and implementation of such documents. As such, CMS does not have the legal authority to broadly preempt, through regulation or other administrative action, those State laws that relate to advance directives.

In regard to current CMS regulations related to advance directives, we note that the provider agreement regulations at § 489.102, referenced by § 482.13, specify very limited instances in which services or procedures specified in a State-recognized advance health care directive may be refused. Section 489.102(c)(2) is limited to refusals to provide services or procedures called for in an advance health care directive, as described in § 489.102(a)(1)(ii)(C), which refers specifically to "the range of medical conditions or procedures affected by the conscience objection." We believe that this narrow window allowing for certain objections to the content of an advance directive would not allow a health care provider to refuse to honor those portions of a State-recognized advance directive that designate an individual as the patient's representative, support person, or health care decision-maker, since such designation is not a medical condition or procedure.

Comment: Some commenters noted a variety of barriers that inhibit the establishment of an advance directive. Such barriers include the cost associated with obtaining legal counsel to help establish an advance directive that is legal in the patient's State, a lack of knowledge about the need for and benefits of an advance directive, an overall cultural apathy towards advance care planning as indicated by the low percentage of the population that has an advance directive, and the [*70842] disadvantages faced by non-English-proficient individuals.

Response: In the proposed rule, we solicited comment on whether the current requirement (at § 482.13(b)(2), which is intended to ensure a patient's right to designate a representative to make informed decisions about his or her care) effectively addresses any inappropriate barriers to a patient's ability to designate a representative, and whether it consistently ensures the right to designate a representative for all patients in all Medicare- and Medicaid-participating hospitals. We also stated our intention to consider public comments received in response to this request as we consider any revision to the current regulation that would eliminate any inappropriate restriction or limitation on a patient's ability to designate a representative that may be permitted under the existing regulation.

In light of our direct solicitation of comments on this issue, we greatly appreciate the comments offered here regarding various barriers that a patient may experience when attempting to designate a representative for health care decision-making purposes. We will give due consideration to these comments when we contemplate future rulemaking in this area of the CoPs.

Comment: Commenters observed that in addition to establishing an advance directive, patients, representatives, and support persons must also be able to produce the document in a time of urgent need. These commenters also observed that being able to do so may be challenging and inconvenient for people, given the nature of urgent medical situations.

Response: Urgent situations are, by nature, unplanned. As such, patients, representatives, and support persons may not have ready access to the necessary medical documentation at the time that the urgent situation occurs. In addition to keeping such documentation in a readily accessible physical location, we are aware of the existence of advance directive registries that store advance directives and other legal documents in an electronic format that can be retrieved by individuals and health care facilities alike. Such document storage and access facilities may be an appropriate source of the proper documentation in urgent situations.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

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

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Condition of Participation: Patient's Rights (β 482.13)

Section β 482.13(h) requires a hospital to have written policies and procedures regarding the visitation rights of patients, including any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. Specifically, the written policies and procedures must contain the information listed in β 482.13(h)(1) through (h)(4). The burden associated with this requirement is the time and effort necessary for a hospital to develop written policies and procedures with respect to visitation rights of patients and to distribute that information to the patients.

We believe that most hospitals already have established policies and procedures regarding visitation rights of patients. Therefore, we are adding only a minimal amount of additional burden hours to comply with this requirement. Additionally, we believe that most hospitals include the visitation policies and procedures as part of their standard notice of patient rights. The burden associated with the notice of patient rights is currently approved under OMB control number 0938-0328. We will be submitting a revision of the currently approved information collection request to account for the following burden.

We estimate that 4,860 hospitals must comply with the aforementioned information collection requirements. We further estimate that it will take each hospital 0.25 hours to comply with the requirement in proposed β 482.13(h). The total estimated annual burden associated with this requirement is 1,215 hours at a cost of \$ 71,746.

B. ICRs Regarding Condition of Participation: Provision of Services (β 485.635)

Section 485.635(f) requires a CAH to have written policies and procedures regarding the visitation rights of patients, including any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation. Specifically, the written policies and procedures must contain the information listed in β 485.635(f)(1) through (f)(4). The burden associated with this requirement is the time and effort necessary for a CAH to develop written policies and procedures with respect to visitation rights of patients and to distribute the information to the patients.

We believe that most CAHs already have established policies and procedures regarding visitation rights of patients. These policies and procedures are most likely included as part of a CAH's patient care policies as required for CAHs under β 485.635. Therefore, we are adding a minimal amount of additional burden hours to comply with this requirement. We will be submitting a revision of the ICR currently approved under OMB control number 0938-1043 to account for the burden associated with the requirements in β 485.635.

We estimate that 1,314 CAHs must comply with the aforementioned information collection requirements. We further estimate that it will take each CAH 0.25 hours to comply with the requirement at β 482.13(h). The total estimated annual burden associated with this requirement is 329 hours at a cost of \$ 19,398.

Table 1--Annual Recordkeeping and Reporting Requirements

Regulation section(s)	OMB control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)
β 482.13	0938-0328	4,860	4,860	.25	1,215
β 485.635	0938-1034	1,314	1,314	.25	329
Total		6,174	6,174		1,544

Table 1--Annual Recordkeeping and Reporting Requirements

Regulation	Hourly labor	Total labor	Total capital/	Total cost
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section(s)	cost of reporting ($\text{\$}$)	cost of reporting ($\text{\$}$)	maintenance costs ($\text{\$}$)	($\text{\$}$)
B 482.13	59.05	71,746	0	71,746
B 485.635	58.96	19,398	0	19,398
Total				91,144

IV. Regulatory Impact Statement

We have examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($\text{\$}$ 100 million or more in any 1 year). This rule does not reach the $\text{\$}$ 100 million economic threshold and therefore is not considered a major rule under the Congressional Review Act.

We believe that the benefits of this rule will amply justify its relatively minimal costs. Executive Order 12866 explicitly requires agencies to consider non-quantifiable benefits, including "distributive impacts" and "equity," and the benefits of the final rule, in these terms, will be significant. In the words of Executive Order 12866, these benefits are "difficult to quantify, but nevertheless essential to consider."

More specifically, the benefits of this rule include: (1) Ensuring the protection of a patient's ability to designate who may and may not visit the patient;

(2) broadening patient participation in the care received (a benefit that would have, among other things, significant emotional benefits for many patients); and

(3) creating a more patient-designated support system, with potentially large improvements in hospital and CAH experiences and health outcomes for patients.

The cost of implementing these changes will largely be limited to the one-time cost related to the revisions of hospital and CAH policies and procedures as they relate to the requirements for patient visitation rights. There will also be the one-time cost of producing a printed page detailing the patient visitation rights that will be provided to patients upon admission. We have estimated the total cost of revising the policies and procedures related to patient visitation rights as well as the total cost of producing a printed page detailing these rights that will be provided to hospital and CAH patients upon admission. No burden is being assessed on the communication of these revisions to hospital and CAH staff or on the distribution of the visitation rights to patients that will be required by this rule, as these practices are usual and customary business practices.

CMS data, as of March 31, 2010, indicated that there were 4,860 hospitals and 1,314 CAHs (for a total of 6,174) in the United States. We prepared the cost estimates for hospitals and CAHs together since both types of providers will be required to perform the same functions. Regarding the costs of revising hospital and CAH policies and procedures as related to the proposed patient visitation rights requirements, this function will be performed by the hospital or CAH administrator at an hourly salary (including a 35 percent benefits) of $\text{\$}$ 59.05 (based on wage estimates for a Medical and Health Services Manager in the May 2009 National, State, Metropolitan, and Nonmetropolitan Area Occupational Employment and Wage Estimates report from the Bureau of Labor Statistics) and that this function will require approximately 15 minutes of an administrator's time to accomplish. Therefore, the total one-time cost for all hospitals and CAHs would be $\text{\$}$ 59.05 x .25 hours x 6,174 total hospitals/CAHs = $\text{\$}$ 91,144.

The most recent CMS figures from 2008 also indicate that there were 37,529,270 total hospital (and CAH) patient admissions in that year. Using that as an estimate, we then calculated the total cost for hospitals and CAHs to produce a

one-page printed disclosure form detailing the patient visitation rights that would be provided to all patients upon admission. We estimated the cost of production to be 2 cents per page. Therefore, the total estimated cost for all hospitals and CAHs to produce this one-page printed patient visitation rights disclosure form and provide it to all patients upon admission (based on the most recent hospital admission figures) will be 37,529,270 total hospital patient admissions x \$ 0.02 = \$ 750,585 for the first year. We will anticipate that this form would be incorporated into hospital and CAH admission materials for subsequent years; therefore, we have no way to estimate the future costs to provide this form, but expect the costs to be minimal once all hospitals and CAHs have incorporated this disclosure of patient visitation rights. In conclusion, the total first-year cost for all hospitals and CAHs to meet the requirements of the patient visitation rights will be \$ 841,729. We believe that the annual benefits of the rule, though not susceptible to quantification, far exceed that amount.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$ 7.0 million to \$ 34.5 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because the Secretary has determined that this rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This 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 for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) [*70844] of the Act because the Secretary has determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$ 100 million in 1995 dollars, updated annually for inflation. In 2010, that threshold is approximately \$ 135 million. This rule will have no consequential effect on State, local, or tribal governments in the aggregate or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Because this regulation will not impose any substantial costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

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

List of Subjects

42 CFR Part 482

Grant programs--Health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

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

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

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 1395(hh)).

2. Section 482.13 is amended by adding a new paragraph (h) to read as follows:

§ 482.13 Condition of participation: Patient's rights.

* * * * *

(h) *Standard: Patient visitation rights.* A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation. A hospital must meet the following requirements:

(1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section.

(2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

PART 485--CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

3. The authority citation for Part 485 continues to read as follows:

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

4. Section 485.635 is amended by adding a new paragraph (f) to read as follows:

§ 485.635 Condition of participation: Provision of services.

* * * * *

(f) *Standard: Patient visitation rights.* A CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation. A CAH must meet the following requirements:

(1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, in advance of furnishing patient care whenever possible.

(2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare--Hospital Insurance; and Program No. 93.774, Medicare--Supplementary Medical Insurance Program). (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program).

Dated: October 21, 2010.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: November 15, 2010.

75 FR 70831, *

Kathleen Sebelius,

Secretary.

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