

incorporating by reference the State's hazardous waste program as an immediate final rule. The EPA did not make a proposal prior to the immediate final rule because we believe these actions are not controversial and do not expect comments that oppose them. We have explained the reasons for this codification and incorporation by reference in the preamble to the immediate final rule. Unless we get written comments which oppose this incorporation by reference during the comment period, the immediate final rule will become effective on the date it establishes, and we will not take further action on this proposal. If we get comments that oppose these actions, we will withdraw the immediate final rule and it will not take effect.

We will then respond to public comments in a later final rule based on this proposal. You may not have another opportunity for comment. If you want to comment on this action, you must do so at this time.

DATES: Send written comments by July 28, 2010.

ADDRESSES: Send written comments to Alima Patterson, Region 6 Regional Authorization Coordinator, OR Julia Banks, Codification Coordinator, State/Tribal Oversight Section (6PD-O), Multimedia Planning and Permitting Division, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733, Phone numbers: (214) 665-8533 or (214) 665-8178. You may also submit comments electronically or through hand delivery/courier; please follow the detailed instructions in the **ADDRESSES** section of the immediate final rule which is located in the Rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Alima Patterson, (214) 665-8533 or Julia Banks, (214) 665-8178.

SUPPLEMENTARY INFORMATION: For additional information, please see the immediate final rule published in the "Rules and Regulations" section of this **Federal Register**.

Dated: April 30, 2010.

Lawrence E. Starfield,

Acting Regional Administrator, Region 6.

[FR Doc. 2010-15329 Filed 6-25-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 482 and 485

[CMS-3228-P]

RIN 0938-AQ06

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare conditions of participation for hospitals and critical access hospitals (CAHs) to ensure the visitation rights of all patients. Medicare- and Medicaid-participating hospitals and CAHs 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 or CAH may need to place on such rights as well as the reasons for the clinical restriction or limitation.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 27, 2010.

ADDRESSES: In commenting, please refer to file code CMS-3228-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this proposed regulation to <http://www.regulations.gov>. Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3228-P, P.O. Box 8010, Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human

Services, Attention: CMS-3228-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: CDR Scott Cooper, USPHS, (410) 786-9465. Marcia Newton, (410) 786-5265. Jeannie Miller, (410) 786-3164.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid

Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

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 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 and close friends who provide them comfort and support do not fit into a traditional concept of "family."

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 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 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 propose patient visitation rights in regulations, we have focused on developing proposed requirements that would 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. Accordingly, the proposed visitation rights requirement, which would require hospital and CAH compliance as a condition of participation in the Medicare and Medicaid programs (see Section II below for further discussion of the regulatory requirements of participation in the Medicaid program), not only addresses the President's directives regarding this important proposed patient right, but also would ensure that all hospitals and CAHs fully inform patients (or their designated representatives) of this right and that all patients are guaranteed full participation in designating who may and who may not visit them.

We believe that such a requirement would need to be broad in scope (that is, would need to apply to all patients and all visitors as designated by the patient (or the patient's representative)). In addition, we believe that the requirement would need to be flexible enough in its application to permit the

hospital or CAH to require written documentation of patient representation by legally valid advance directives, such as durable powers of attorney and healthcare proxies (as opposed to verbal designation of the representative by the patient), but only in rare cases. In such cases, the patient's documented representative could specify which visitors are and are not allowed to see the patient. We seek comment on how best to identify these rare cases. We believe that, at a minimum, a hospital or CAH may not require documentation where 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. We recognize that many States, such as Delaware, Minnesota, Nebraska, and North Carolina (as mentioned in the Presidential Memorandum), have already taken the lead in this area and adopted laws that directly address these types of issues. Finally, we believe that a patient visitation rights requirement also would need to accommodate medically appropriate visitation policies generally recognized by the Nation's hospitals and CAHs, *i.e.*, those that set forth any clinically necessary or reasonable restrictions or limitations on visitors (for example, when the patient is undergoing care interventions, when there may be infection control issues, or when visitation may interfere with the care of other patients).

In the April 15, 2010 Presidential Memorandum, the President also emphasized the consequences that restricted or limited visitation has for patients. 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 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."

While the Presidential Memorandum specifically called for patient visitation rights in hospitals (and, by natural extension, CAHs since they are also hospitals, but with separate and distinct CoPs under the Medicare and Medicaid programs), there are other Medicare and Medicaid providers with respect to which the issue of patient visitation rights also may factor into the degree to which patients receive appropriate and compassionate care. Both the existing hospice CoPs and the nursing home requirements in the Medicare and Medicaid programs contain provisions that address visitors directly. The existing inpatient hospice CoP at 42 CFR 418.100(e) provides that "[p]atients must be permitted to receive visitors at any hour, including small children," and contains another provision that requires hospices to provide privacy for patients and their family members when they are residing in the inpatient setting. The existing resident rights provision within the nursing home requirements under 42 CFR 483.10(j) contains even more extensive provisions concerning the rights of residents to receive visitors, including the right at any time to withdraw or deny consent to immediate family members, other relatives, or other individuals who are visiting the resident. While neither the hospice

CoPs nor the nursing home requirements contains regulatory language that expressly prohibits the denial of visitation privileges based on race, color, national origin, religion, sex, sexual orientation, gender identity, or disability, as contemplated by the April 15, 2010 Presidential Memorandum with respect to hospitals, we believe that these existing acknowledgements of the visitation rights of hospice patients and nursing home residents can operate to fulfill the spirit of the Presidential Memorandum; that is, to ensure the protection of all patients' right to designate who may and may not visit the patient. Through this notice of proposed rulemaking, we are soliciting comments on the issue of patient visitation requirements with regard to these and other Medicare and Medicaid providers and suppliers.

II. Provisions of the Proposed Regulation

The following provisions of this proposed rule would apply to all hospitals and CAHs participating in the Medicare and Medicaid programs. 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 the hospital's patients. Under this authority, the Secretary has established in the regulations at 42 CFR part 482 the requirements that a hospital must meet 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, § 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 qualify for participation in Medicaid.

We are proposing to incorporate the proposed visitation rights requirement for hospitals as a new standard within the patient rights CoP at § 482.13. 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 proposed

requirements, we are proposing to specify that 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 are further proposing 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 are specifically seeking public comments on the style and form that patient notices or disclosures would need to follow so that patients would be best informed of these rights.

Consistent with the previously cited article's conclusions that a denial or restriction of visitation privileges can be inconsistent with the health and safety of patients where the denial is not justified by a medically appropriate reason, we are proposing that hospitals would not be permitted to restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, sexual orientation, gender identity, or disability. In addition, we are proposing 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.

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

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 conditions of participation 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 representative 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 representative, 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.

The requirement at § 482.13(b)(2) is intended to ensure the patient's right to designate a representative. We are taking this opportunity to solicit 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, and consistently ensures the right to designate a representative for all patients in all Medicare- and Medicaid-participating hospitals. We intend 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.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved 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 are soliciting 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 (§ 482.13)

Proposed § 482.13(h) would require 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 proposed § 482.13(h)(1) through (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 will be 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 § 482.13(h). The total estimated annual burden associated with this requirement is 1,215 hours at a cost of \$126,360.

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

Proposed § 485.635(f) would require 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 proposed § 485.635(f)(1) through (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 § 485.635. Therefore, we will be adding only 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 proposed requirements in § 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 in proposed § 482.13(h). The total estimated annual burden associated with this requirement is 329 hours at a cost of \$34,216.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or
2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, [CMS–3228–P]; Fax: (202) 395–6974; or E-mail: OIRA_submission@omb.eop.gov.

IV. Response to Comments

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

V. 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 (\$100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

We believe that the benefits of the rule would amply justify its relatively small costs. Executive Order 12866 explicitly requires agencies to consider non-quantifiable benefits, including “distributive impacts” and “equity,” and the benefits of the proposed rule, in these terms, would 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 the proposed 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 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 proposed changes would largely be limited to the one-time cost related to the revisions of hospital and CAH policies and procedures as they relate to the proposed requirements for patient visitation rights. There would also be the one-time cost of producing a printed page detailing the patient visitation rights that would 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 would 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 would be required by this proposed 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 would 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 would be performed by the hospital or CAH administrator at an hourly salary (including benefits) of \$104 (our salary figures are from <http://www.salary.com/>) and that this function would require approximately 15 minutes of an administrator's time to accomplish. Therefore, the total one-time cost for all hospitals and CAHs would be $\$104 \times .25 \text{ hours} \times 6,174 \text{ total hospitals/CAHs} = \$160,524$.

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) would be $37,529,270 \text{ total hospital patient admissions} \times \$0.02 = \$750,585$ for the first year. We would 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 we would 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 proposed patient visitation rights would be \$0.9 million. 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 we have determined, and the Secretary certifies,

that this proposed rule would 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 603 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) of the Act because we have determined, and the Secretary certifies, that this proposed rule would 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 proposed rule would have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Because this proposed regulation would 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 proposed 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 proposes to amend 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—

(1) Inform each patient (or representative, 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 representative, 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, sexual orientation, gender identity, or disability.

(4) 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.

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—

(1) Inform each patient (or representative, 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 representative, 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, sexual orientation, gender identity, or disability.

(4) 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.

(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: June 18, 2010.

Marilyn Tavenner,

Acting Administrator and Chief Operating Officer, Centers for Medicare & Medicaid Services.

Approved: June 21, 2010.

Kathleen Sebelius,

Secretary.

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DEPARTMENT OF TRANSPORTATION**Pipeline and Hazardous Materials Safety Administration****49 CFR Part 192**

[Docket No. PHMSA-RSPA-2004-19854]

Pipeline Safety: Information Collection Gas Distribution Annual Report Form

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Request for public comments and OMB approval of modifications to an existing information collection.

SUMMARY: As required by the Paperwork Reduction Act of 1995 (PRA), the Pipeline and Hazardous Materials Safety Administration (PHMSA) published a notice in the **Federal Register** on December 4, 2009, under Docket No. PHMSA-2004-19854 of its intent to revise the agency's Gas Distribution System Annual Report Form (PHMSA F 7100.1-1). PHMSA F 7100.1-1 is covered under the PHMSA information collection titled: "Incident and Annual Reports for Gas Pipeline Operators," with an OMB Control Number of 2137-0522. PHMSA is publishing this notice to respond to comments and announce that the revised information collection will be submitted to OMB for approval. This notice also informs operators of gas distribution systems that PHMSA is planning for the revised Annual Report Form, once approved, to be used for the 2010 calendar year and submitted to PHMSA by March 15, 2011. The portion of the annual report relative to mechanical fitting (compression couplings) failures will be delayed by one year and will take effect starting with the 2011 calendar year.

DATES: Submit comments to OMB on or before July 28, 2010.

ADDRESSES: You may submit comments identified by the docket number "PHMSA-2004-19854" and OMB Control Number "2137-0522" by any of the following methods:

• *Fax:* 1-202-395-6566, ATTN: Desk Officer for Department of Transportation (DOT)/PHMSA.

• *Mail:* Office of Information and Regulatory Affairs (OIRA), OMB, 726 Jackson Place, NW., Washington, DC 20503, ATTN: Desk Officer for DOT/PHMSA.

• *E-mail:* OIRA, Office of Management and Budget, at the following address:

oira_submissions@omb.eop.gov (ATTN: Desk Officer for DOT/PHMSA).

Requests for a copy of the information collection should be directed to Cameron Satterthwaite, 202-366-1319 or by e-mail at *Cameron.Satterthwaite@dot.gov*, or by mail at DOT, PHMSA, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001.

FOR FURTHER INFORMATION CONTACT:

Technical Information: Mike Israni, 202-366-4571 or by e-mail at *Mike.Israni@dot.gov*.

Information Collection: Cameron Satterthwaite, 202-366-1319 or by e-mail at *Cameron.Satterthwaite@dot.gov*.