

*Section 403.742 Condition of Participation: Physical Environment*

Section 403.742(a)(4) requires that a RNHCI have a written disaster plan to address loss of power, water, sewage disposal, and other emergencies.

Section 403.742(b)(3) requires that CMS may permit variances in requirements specified in paragraphs (b)(1)(i) and (b)(1)(ii) of this section relating to rooms on an individual basis when the RNHCI adequately demonstrates in writing that the variances meet the requirements of this section.

While this information collection requirement is subject to the PRA, we believe the burden associated with this ICR is exempt as defined in 5 CFR 1320.3(c)(4), since it does not collect information from 10 or more entities on an annual basis.

*Section 403.746 Condition of Participation: Utilization Review*

In summary, § 403.746 states that the RNHCI must have in effect a written utilization review plan to assess the necessity of services furnished. The plan must provide that records be maintained of all meetings, decisions, and actions by the utilization review committee. The utilization review plan must contain written procedures for evaluating the following: Admissions, the duration of care, continuing care of an extended duration, and items and services furnished.

The following sections describe the burden associated with the payment provisions. Based on the most recent data available, Medicare expenditures for Christian Science sanatoria were approximately \$5 million annually. The trigger level for FFY 1998, the first year of RNHCI implementation, was \$20 million. Beginning in FFY 2000, when estimated expenditures for RNHCI services exceed the trigger level for a FFY, CMS must adjust the RNHCI payment rates. Therefore, the burden associated with the following sections is not subject to the PRA at this point in time.

*Section 403.752 Payment Provisions*

Section 403.752(d)(i) states that the RNHCI must notify the beneficiary in writing at the time of admission of any proposed or current proportional Medicare adjustment. A beneficiary currently receiving care in the RNHCI must be notified in writing 30 days before the Medicare reduction is to take effect. The notification must inform the beneficiary that the RNHCI can bill him or her for the proportional Medicare adjustment.

Section 403.752(d)(ii) states that the RNHCI must, at time of billing, provide the beneficiary with his or her liability for payment, based on a calculation of the Medicare reduction pertaining to the beneficiary's covered services permitted by § 403.750(b).

We believe that this ICR is not subject to the PRA, as implemented by 5 CFR 1320.4(a)(2), since the collection action is conducted during an investigation or audit against specific individuals or entities.

*Section 440.170 General Provisions—Medicaid*

Section 440.170(b)(9) states that an RNHCI must provide, upon request, information CMS may require to implement section 1821 of the Act, including information relating to quality of care coverage and determinations.

*Section 489.102 Requirements for Providers*

The ICR in the following section, except for its application to RNHCI, has been approved under OMB approval number 0938–0610.

In summary, § 489.102(a) requires that hospitals, critical access hospitals, skilled nursing facilities, home health agencies, providers of home health care (and for Medicaid purposes, providers of personal care services), hospices, and religious nonmedical health care institutions document and maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care.

For the current approval, we stated that it will take each facility 3 minutes to document a beneficiary's record whether he or she has implemented an advance directive. We anticipate that it will also take each RNHCI 3 minutes per patient to comply with this requirement, for a total of 104 burden hours on an annual basis. In addition, there will be a one-time burden of 8 hours per RNHCI to maintain written policies and procedures concerning advance directives, for a total of 152 hours.

We will submit a revision to OMB approval number 0938–0610 to reflect the addition of RNHCI to the paperwork burden.

We have submitted a copy of this rule to OMB for its review of the ICRs. These requirements are not effective until they have been approved by OMB. A notice will be published in the **Federal Register** when approval is obtained.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: Dawn Willingham, CMS–1909–F, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850; and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn.: Brenda Aguilar, CMS Desk Officer.

**VI. Regulatory Impact Statement**

*A. Overall Impact*

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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 provides religious nonmedical health care institution (RNHCI) inpatient services to individuals qualifying for Medicare or Medicaid benefits, who because of their religious beliefs do not find it appropriate to use conventional medical care. The rule provides for the physical care of these beneficiaries in RNHCI but does not provide payment for the religious component of care. Currently, only 16 RNHCI facilities nationally participate in the program, with expenditure levels approximately \$5 million annually. This rule does not reach the economic threshold and thus is not considered a major rule.

*B. Anticipated Effects*

**1. Effects on Small Business**

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 government agencies. Most hospitals and most other providers and suppliers