circumstances may a financial institution use its own address or another financial institution's address in place of the customer's address, notwithstanding any prior guidance that appeared to allow the use of a financial institution's address under limited circumstances.[5] To avoid any confusion on the issue of addresses in transmittal orders, FinCEN, by this notice, hereby revokes Q&A no. 18 contained in FinCEN Advisory Issue 3 (June 1996) and Q&A no.16 contained in FinCEN Advisory Issue 7 (January 1997). FinCEN anticipates issuing a new set of frequently asked questions and answers regarding the application of the funds transfer rules very shortly. Nothing in this notice affects the obligation of a financial institution to comply with any other requirement imposed under the Bank Secrecy Act, including a customer identification program requirement imposed under Section 326 of the USA Patriot Act.

Finally, to give financial institutions the opportunity to take those steps necessary to comply fully with the Travel Rule, this Notice extends the conditional exception through July 1, 2004.

IV. FinCEN Issuance

By virtue of the authority contained in 31 CFR 103.55(a) and (b), which has been delegated to the Director of FinCEN, the effective period of the CIF Exception, as such Exception is set forth (as part of FinCEN Issuance 98–1, 63 FR 3640 (January 6, 1998)) under the heading ''Grant of Exceptions'' (63 FR 3641) is extended so that CIF Exception will expire on July 1, 2004, for transmittals of funds initiated after that date.

Dated: November 21, 2003.

William F. Baity,

Acting Director, Financial Crimes Enforcement Network.

[FR Doc. 03–29617 Filed 11–26–03; 8:45 am]

BILLING CODE 4810–02–P

address of next of kin or another contact individual for individuals who do not have a residential or business address. For a person other than an individual (such as a corporation, partnership, or trust), ''address'' is a principal place of business, local office, or other physical location. *See* 68 FR 25090 (May 9, 2003) (Final Rules for Customer Identification Programs) issued jointly with the Board of Governors of the Federal Reserve System, Office of the Comptroller of the Currency, Office of Thrift Supervision, Federal Deposit Insurance Corporation, National Credit Union Administration, Commodity Futures Trading Commission, and Securities and Exchange Commission. Note, however, that while the Section 326 rules apply only to new customers opening accounts on or after October 1, 2003, and exempt wire transfers from the definition of ''account'' for banks, the Travel Rule applies to all transmittals of funds of $3,000 or more, whether or not the transmittor is a customer for purposes of the Section 326 rules.

[5] *See* FinCEN Advisory Issue 7, Funds ''Travel'' Regulations: Questions & Answers, January 1997 (Q&A no. 16) (stating that a financial institution must not use its own address ''except where it is the actual address of record of the person'').

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Parts 403, 489 and 498

[CMS–1909–F]

RIN 0938–AI93

Medicare and Medicaid Programs; Religious Nonmedical Health Care Institutions and Advance Directives

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

ACTION: Final rule.

SUMMARY: This final rule implements requirements under the Balanced Budget Act of 1997, which set forth requirements for the new Religious Nonmedical Health Care Institution program and advance directives. This rule finalizes the Medicare requirements for coverage and payment of services furnished by religious nonmedical health care institutions, the conditions of participation that these institutions must meet before they can participate in Medicare, and the methodology we will use to pay these institutions and monitor expenditures for services they furnish. This rule also finalizes the rules governing States' optional coverage of religious nonmedical health care institution services under the Medicaid program. Additionally, this final rule addresses comments we received on the November 30, 1999, interim final rule and also makes minor changes to clarify our policy. Lastly, this rule incorporates a minor change to the requirements for advance directives.

DATES: *Effective date:* These regulations are effective December 29, 2003.

FOR FURTHER INFORMATION CONTACT:

Jean-Marie Moore, (410) 786–3508 (for general information, Medicare coverage, and payment issues);

Nancy Archer, (410) 786–0596 (for Medicare conditions of participation issues); and Linda Tavener, (410) 786–3838 (for Medicaid issues).

SUPPLEMENTARY INFORMATION:

Copies: This **Federal Register** document is available from the Federal Register online database through *GPO access,* a service of the U.S. Government Printing Office. The Web site address is *http://www.access.gpo.gov/nara/index.html.*

I. Background

Section 4454 of the Balanced Budget Act of 1997 (BBA '97), (Pub. L. 105–33, enacted August 5, 1997) provides for removal of all statutory and regulatory references to Christian Science sanatoria, and for coverage and payment of inpatient hospital services and post-hospital extended care services furnished in qualified religious nonmedical health care institutions (RNHCIs) under Medicare and as a State Plan option under Medicaid. (We will refer to these services as ''RNHCI services.'') The new amendments make it possible for institutions other than Christian Science facilities to qualify as RNHCIs and to participate in Medicare and Medicaid.

On November 30, 1999, we published an interim final rule in the **Federal Register** (67 FR 67028) to implement the BBA '97 amendments that set forth the requirements for coverage and payment for services furnished by RNHCIs, and modified the rules regarding advance directives.

Specifically, the interim final rule presented the methodologies under which we will pay RNHCIs, monitor the Medicare expenditure level for RNHCI secular services for any given federal fiscal year (FFY), and implement a statutory ''sunset'' of the RNHCI benefit. In addition, the rule set forth the conditions of participation that an RNHCI must fully meet to participate in the Medicare program and revised Medicaid regulations to reflect statutory changes and made necessary nomenclature and conforming changes. Finally, the rule revised the regulations pertaining to advance directives for all providers.

II. Provisions of the Interim Final Rule

Below we provide a brief summary of the provisions we implemented in the November 30, 1999, interim final rule to comply with requirements set forth by section 4454 of BBA '97.

A. RNHCI Medicare Benefits, Conditions of Participation, and Payment

1. Basis and Purpose (§ 403.700)

This subpart implemented sections 1821; 1861(e), (y) and (ss); 1869; and 1878 of the Social Security Act (the Act) regarding Medicare payment for inpatient hospital or post-hospital extended care services furnished to eligible beneficiaries in RNHCIs.

2. Definitions and Terms (§ 403.702)

Under this section, we included definitions for terms or acronyms used in the rule. Those terms that were defined elsewhere within the text of the rule were not included under this section.

3. Conditions for Coverage (§ 403.720)

Under this section, we specified the 10 qualifying provisions as contained in section 1861(ss)(1) of the Act that a Medicare or Medicaid provider must satisfy to meet the definition of an RNHCI. While the requirements contained in sections 1861(ss)(1)(B) (lawful operation), (G) (ownership by or in a provider of medical services), and (H) (utilization review) of the Act were explicitly addressed in the Medicare Conditions of Participation before passage of the BBA '97, it is essential that a facility meet all 10 elements to qualify as an RNHCI for both the Medicare and Medicaid programs.

In addition to meeting the definition of an RNHCI, the facility must also meet conditions of coverage for RNHCI services as established under section 1821 of the Act. Specifically, section 1821(a) of the Act requires that as a condition for Part A Medicare coverage, the beneficiary must have a condition that would qualify under Medicare Part A for inpatient hospital services or extended care services furnished in a hospital or skilled nursing facility that is not an RNHCI. The beneficiary must also have a valid election in effect to receive RNHCI services.

The RNHCI may not accept a patient as a Medicare or Medicaid beneficiary after the sunset provision (§ 403.756) is implemented, unless the patient has an election in effect before January 1 of the year in which the sunset provision is implemented. A claim filed for payment for services furnished to a patient with no valid election in effect before January 1 of the year the sunset provision is implemented would be denied. We explain the circumstances in which the sunset provision would be triggered at § 403.750 of the regulations.

4. Valid Election Requirements (§ 403.724)

Under this section, we implemented section 1821(b) of the Act to address the issues involved in beneficiary election of RNHCI services. We specified the general requirements relating to the election and the election process as well as the written statements that must be included in the election form. In addition, we described the circumstances under which the election would be revoked. Finally, we discussed the limitations that apply to subsequent elections.

5. Conditions of Participation

Under section 1861(ss)(1)(J) of the Act, we may accept an RNHCI as a participating Medicare provider only if, in addition to meeting the specific requirements of that section, it meets other requirements we find necessary in the interest of patient health and safety. With the broad authority the Act gave us to impose these requirements, we set forth those conditions we found to be appropriate and necessary in the religious nonmedical setting that an RNHCI must meet to participate in the Medicare program. We set forth conditions of participation regarding patient rights (§ 403.730); quality assessment and performance improvement (§ 403.732); food services (§ 403.734); discharge planning (§ 403.736); administration (§ 403.738); staffing (§ 403.740); physical environment (§ 403.742); life safety from fire (§ 403.744); and utilization review (UR) (§ 403.746).

Life Safety from Fire. In the interim final rule we required that an RNHCI comply with the 1997 edition of the National Fire Protection Association (NFPA) Life Safety Code that we incorporated by reference. We discuss the update to the Life Safety Code later in this rule.

Utilization Review. This was the only condition of participation specifically required by statute. Section 1861(ss)(1)(H) of the Act requires that an RNHCI have in effect a UR plan that includes the establishment of a UR committee to carry out the functions of the program.

6. Estimate of Expenditures and Adjustments (§ 403.750)

Section 1821(c)(1) of the Act requires us to estimate the level of Medicare expenditures for RNHCI benefits before the beginning of each Federal fiscal year (FFY) and requires us to monitor the expenditure level for RNHCI services provided in each FFY. The estimation of expenditure levels is necessary to determine if adjustments are required to limit payments to RNHCIs in the following FFY. In addition, the estimate is used to determine if the sunset provision is implemented.

As required by section 1861(e) of the Act, we will issue an annual Report to Congress, reviewed by the Office of Management and Budget, as the vehicle for reporting the potential need to make adjustments in payments and proposed mechanisms to be employed in order to stay within the established expenditure ''trigger level'' which is defined in section 1821(c)(2)(C) of the Act as the ''unadjusted trigger level'' for an FFY, adjusted using the consumer price index to the last 12 months ending July of the prior FFY, and increased or decreased by the carry forward from the previous FFY. In the interim final rule, we provided descriptions and examples of the trigger level calculation, the carry forward calculation, estimated expenditures, and adjustments in payments to help explain the statutory provision (64 FR 67036).

Section 1821(c)(2)(A) of the Act provides for a proportional reduction in payments for covered RNHCI services when the level of estimated expenditures exceeds the trigger level for any FFY. In addition to a proportional reduction in payments, section 1821(c)(2)(B) of the Act authorizes us to impose other conditions or limitations to keep Medicare expenditure levels below the trigger level. The statute provides us with authority to decide which type of adjustment to apply but is silent about when to apply a proportional adjustment or when to apply alternative adjustments. Therefore, we have extremely broad authority to decide what type of adjustments to impose.

The regulations at § 403.750 implement the statute and provide for imposing either a proportional adjustment to payments or alternative adjustments, depending on the magnitude of the adjustment required to keep the level of estimated expenditures from exceeding the trigger level. To account for any error in the estimation of expenditure levels, the trigger level for the next FFY is adjusted by the ''carry forward.'' If expenditures were to exceed the trigger level, the trigger level for the subsequent year must be decreased, resulting in more drastic payment adjustments in future years. We will do this in an attempt to prevent expenditures from exceeding the trigger level for 3 consecutive years and thus avoid having to implement the sunset provision.

7. Payment Provisions (§ 403.752)

Payment to RNHCIs. Sections 1861(e) and (y)(1) of the Act grant us broad authority to construct a payment methodology for RNHCIs. We specified that we would continue to pay RNHCIs under the same reasonable cost methodology we used for Christian Science sanatoria. We pay RNHCIs the reasonable cost of furnishing covered services to Medicare beneficiaries subject to the rate of increase limits in accordance with the provisions in 42 CFR 413.40, which implement section 101 of the Tax Equity and Fiscal

Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248).

We added that we intended to continue paying all RNHCIs under a reasonable cost, subject to the rate of increase limit methodology, until we identify an appropriate prospective payment methodology to meet the special requirements for this provider group. In the interim final rule, we removed and reserved § 412.90(c) and § 412.98 for the RNHCI prospective payment.

Administrative and Judicial Review. Under section 1821(c)(2)(D) of the Act, there is no administrative or judicial review of our estimates of the level of expenditures for RNHCI services or the application of the adjustment in payments for those services. We incorporated this provision into our regulations.

Beneficiary Liability. Under the new regulations, RNHCIs are subject to Medicare rules for deductibles and coinsurance. Under normal Medicare rules, a provider of services may only bill a beneficiary deductible and coinsurance amounts. However, section 1821(c)(2)(E) of the Act authorizes RNHCIs to bill individuals an amount equal to the reduction in payments applied under sections 1821(c)(2)(A) or (B) of the Act. We implemented this provision specifying that when payments are reduced to prevent estimated expenditures from exceeding the trigger level, the RNHCI may bill the beneficiary the amount of the Medicare reduction attributable to his or her covered services. In addition, we set forth the requirements an RNHCI must follow regarding notifying a beneficiary of any current or proposed Medicare adjustments.

8. Monitoring Expenditure Level (§ 403.754)

Under this section, we implemented section 1821(c)(3)(A) of the Act that requires us to monitor the expenditure level of RNHCIs beginning with FFY 1999 which allows us to calculate the carry forward.

9. Sunset Provision (§ 403.756)

Section 1821(d) of the Act contains the RNHCI sunset provision. This provision, when activated, will prevent beneficiaries from making elections to receive Medicare payment for religious nonmedical health care services after a certain date. The sunset provision will be activated when the level of estimated expenditures exceeds the trigger level for three consecutive FFYs.

In accordance with this statutory provision, we specified in our regulations under this section that beginning FFY 2002, if the level of estimated expenditures for all RNHCIs exceeds the trigger level for 3 consecutive FFYs, we would not accept any Medicare claims for payment for any election executed on or after January 1 of the following calendar year. We also specified in the interim final rule that we would publish a notice in the **Federal Register** at least 60 days before the effective date of the sunset provision to alert the public that no elections will be accepted for services in an RNHCI.

B. Medicaid Provisions (§ 440.170)

Services in RNHCIs are optional Medicaid services that a State may elect to include in its title XIX State plan in accordance with section 1905(a)(27) of the Act. This section permits the inclusion of any other medical care and any other type of remedial care recognized under State law, specified by CMS. Federal financial participation is only available to a State for these services if they are included in the State Plan.

Section 4454(b) of the BBA '97 provides for coverage of a religious nonmedical health care institution as defined in section 1861(ss)(1) of the Act. Specific ownership and affiliation requirements related to RNHCIs are described in section 1861(ss)(4) of the Act. We therefore revised § 440.170(c), ''Services in Christian Science sanitoriums,'' to accommodate the new RNHCI program. Additionally, an RNHCI as defined in section 1861(ss)(1) of the Act furnishes exclusively inpatient services. Consequently, we revised § 440.170(b), ''Services of Christian Science nurses,'' since it dealt with Christian Science and care in the home setting. We revised language at § 440.170(b), to define an RNHCI for Medicaid coverage purposes as one that meets the requirements of section 1861(ss)(1) of the Act, and § 440.170(c), to describe the specific ownership and affiliation requirements applicable to Medicaid RNHCIs. In addition, we specified in the interim final rule that RNHCIs are required to meet the Medicare conditions of participation described in part 403 of this rule in order to be eligible to receive payment under Medicaid, rather than developing separate Medicaid requirements.

C. Part 488 Survey, Certification, and Enforcement Procedures

Section 1861(ss)(2) of the Act provides that we may accept the accreditation of an approved group that RNHCIs meet or exceed some or all of the applicable Medicare requirements. Therefore, in the interim final rule, we amended the regulations at § 488.2 to add section 1861(ss)(2) of the Act as the statutory basis for accreditation of RNHCIs and § 488.6 to add the RNHCIs to the list of providers in this section.

D. Part 489, Subpart I—Advance Directives

Section 4641 of the BBA '97 required that (for all providers entering into a provider agreement with CMS) an individual's advance directive be placed in a ''prominent part'' of his or her medical record. As this was such a minor change to our requirements at section 489, we requested that this change be appended to the RNHCI regulation, thereby avoiding a separate rulemaking process. Therefore, in the November 30, 1999 final rule, we added ''prominent part'' to § 489.102(a)(2) to reflect this requirement. That is, providers are required to document an advance directive in a prominent part of the individual's current medical record.

III. Analysis of and Responses to Comments

We received a total of three items of correspondence on the interim final rule with comment published on November 30, 1999. The comment response on the interim final rule was very limited, and there were no similarities in issues raised by the commenters. We received comments from a fire safety association; a pediatric medical association; and a national religious organization that is oriented to healing by prayer. Each commenter approached the final rule in a manner that reflected the views of his or her particular organization. The major issues that commenters raised included the following:

- A prohibition on the admission of children to an RNHCI.
- Incorporation of a specific version of the fire safety code in the rule.
- Modification of the requirements to correspond to the beliefs of a specific religious group.
- Modification of the requirements related to the election process and the related coverage of services.
- Modification of the prohibition on the use of restraints.

We are not making any changes in the regulation as a result of the three comments we received, although we note that one change, regarding the Life Safety Code, was made in a separate rule on January 10, 2003, with an effective date of March 11, 2003 (68 FR 1374). We summarized the issues raised by each commenter and have provided our responses below.

A. Pediatric Medical Association

Sections 403.702, 403.730, and 440.170

Comment: One commenter suggested amending the conditions of participation explicitly to prohibit RNHCIs from providing care to any child, regardless of whether the individual is seeking payment under Medicare or Medicaid for that care. The comment is based on the statutory language that authorizes the Secretary to establish standards to ensure the health and safety of patients choosing to receive care in RNHCIs. The commenter believes that it is impossible to ensure the health and safety of children who are patients in an RNHCI because the patient is isolated from persons competent or willing to assess the need and appropriately secure medical care when the care is necessary to preserve the child's life or health. The commenter added that the Secretary has the authority to prohibit RNHCIs from providing services to children and should do so.

Response: We do not have the authority to exclude any patients, including children, from admission to an RNHCI. Nevertheless, our data indicate that no children have sought RNHCI services as program beneficiaries thus far. The reason for this situation is that, in at least some instances, children must undergo some type of medical examination before they can obtain benefits under Medicare and Medicaid. For example, a child can only receive Medicare benefits if he or she has undergone a medical physical examination and as a result was determined to meet Social Security criteria for disability. Such an examination is inconsistent with opposition to receipt of traditional medical care. For these reasons, we believe few if any children will be admitted to RNHCIs as Medicare or Medicaid beneficiaries. Therefore, we will not revise the conditions of participation as the commenter suggested.

B. Religious Nonmedical Organization

Definitions and Terms—§ 403.702

Comment: The commenter requested that the definition for ''religious nonmedical care or religious method of healing'' be removed or revised as follows:

Religious nonmedical care or religious method of healing'' means health care furnished in accordance with a religious belief or doctrine with which the acceptance of conventional or unconventional medical care by a beneficiary would be inconsistent.

The commenter argued that our current definition, ''health care furnished under established religious tenets that *prohibited* conventional or unconventional medical care for the treatment of a beneficiary, and *the sole reliance on these religious tenets,*'' if interpreted literally, could actually prohibit religious nonmedical nursing facilities from qualifying as RNHCIs that the Congress clearly intended to be qualified.

The commenter indicated that their method of healing did not include the use of conventional or unconventional care and that the teachings of this Church did not expressly ''prohibit'' the choice of medical treatment. The commenter stated that the choice of treatment rested with the individual, but an individual would not be practicing his or her religion while receiving medical care. The commenter further stated that this is why practicing members of the group, relying entirely on spiritual means for healing, required accommodation in order to participate in Medicare. The commenter indicated that many members of their group engaged in a number of practices that involved neither the acceptance of medical treatment nor reliance on religious ''tenets'' but were undertaken in the interest of practicing good care of their ''health.'' The commenter sought more flexibility for a beneficiary to select some forms of health care that are nonintrusive such as visiting dentists for oral hygiene; visiting an optometrist or wearing eyeglasses; or being fitted for or wearing a mechanical hearing aid.

Additionally, the commenter expressed that the definition of ''religious nonmedical care or religious method of healing'' was neither required by nor consistent with the Act, and that Constitutional issues have been raised regarding the use of the term ''established religious tenets.''

Response: Both the statute and the related legislative history demonstrate a clear congressional intent to establish this benefit for those who for religious reasons are conscientiously opposed to acceptance of medical care and to provide parameters for nonexcepted medical treatment. Since both the law and the congressional deliberations are clear on the issue, the rule must follow the statutory intent and provide a framework for all religious groups that may use the benefit. The rule must be applicable to all in the intended benefit group, not to just a sector of the potential beneficiaries. With regard to a beneficiary's choice or need to receive such services as oral hygiene visits, optometry visits or eyeglasses, or testing and fitting for hearing aids, it should be noted that Medicare does not cover these services and that they are the financial responsibility of the individual.

The use of the term ''religious tenet'' is considered appropriate to cover the basic beliefs of any religious group that is seeking participation in the RNHCI program. While the use of the term is not prescribed by the statute, the development of regulations does provide the opportunity to use other language and the term ''religious tenets'' is consistent with the Act. Federal courts have repeatedly upheld the constitutionality of these provisions. *See,* for example, *Kong* v. *Min De Parle,* No. C 00–4285 CRB, 2001 WL 1464549 (N.D.Cal. Nov. 13, 2001) (upholding constitutionality of section 4454 of the BBA); *see also Children's Healthcare is a Legal Duty, Inc.* v. *Min De Parle,* 212 F.3d 1084 (8th Cir. 2000), *cert. den.*, 532 U.S. 957, 121 S.Ct. 1483 (2001) (same). We are making no changes to the terms ''religious nonmedical care'' or ''religious method of healing.''

Comment: The commenter suggested that we provide a more flexible definition of ''religious nonmedical nursing personnel'' to provide the RNHCI more latitude in hiring outside their religious denomination, if they so choose. The commenter indicates that constitutional issues may be raised by the requirement that nursing personnel ''be grounded in the religious beliefs of the RNHCI.'' The commenter stated that the Act only requires personnel to be ''experienced in caring for the physical needs of these patients.''

Additionally the commenter would appreciate it if the regulations could clearly state that nursing personnel who are less experienced, such as trainees, may provide service to patients under the supervision of those who are ''formally recognized as competent in the administration of care within their religious nonmedical health care group.'' The commenter assumed that the regulations did not prohibit RNHCIs from allowing trainees to provide service to patients when supervised by experienced personnel but requested that we provide clarification in the regulation.

Response: Medical model health care settings use registered nurses or licensed practical nurses that have participated in educational programs and following graduation take standardized tests for licensure. The statute requires that for payment purposes a beneficiary would require hospital or skilled nursing facility care in order to qualify for admission to an RNHCI. In turn, by statute the RNHCI may provide only nonmedical nursing

items and services to patients, which is contrary to conventional nursing practice. Currently the only standardization for RNHCI nurse credentials exists for those individuals prepared in religious group nurse training programs and involved in the practice of that religion.

The phrase ''grounded in the religious beliefs'' of an RNHCI is not intended to mean that religious nonmedical nursing personnel must ''accept or practice'' a particular religious belief. The phrase ''grounded in the religious beliefs'' means that nonmedical nursing personnel must be appropriately familiar with the culture and religious beliefs of the RNHCI to care for the physical needs of patients.

For purposes of writing the rule, it was necessary to choose those requirements that would provide a level of standardization for providing nonmedical nursing care to beneficiaries. We are retaining the definition of religious nonmedical nursing personnel as set forth in the interim final rule.

Similar to other provider types, the issue of nurse trainees was not addressed in the rule. The per-diem rate includes payment for RNHCI nurses responsible for the care of beneficiaries, and they may also supervise those aspects of care provided by trainees. While trainees can provide care under the supervision of an RNHCI nurse, any cost or payment attributed to the trainee is not to be considered a component of the Medicare or Medicaid per diem rate.

Comment: The commenter suggested that we expand the term ''legal representative'' that is included in the definition of ''election'' to include someone acting under a valid health care durable power of attorney or an equivalent instrument.

Response: The term ''legal representative'' as used in the definition of ''election'' is considered appropriate to safeguard the interest of the beneficiary, and we are not making any revisions. The designation of a legal representative is a serious responsibility that should follow accepted legal protocols and therefore does not require further definition in the rule. In this matter, we generally defer to the States in deciding who qualifies as a ''legal representative'' since State law governs these questions.

Elections and Revocations § 403.724

Comment: The commenter suggested that for practical purposes an election be considered valid without notarization under certain circumstances. The commenter requested a grace period to cover those periods when the business office is not open, such as evenings, nights, weekends, and holidays.

Response: Since we consider obtaining notary authority for individual staff members to be a relatively straightforward process, there can be several notaries in a facility to meet beneficiary needs when the business office is not open. Additionally, the RNHCI can establish relationships with notaries within the community to provide assistance in emergency situations. Therefore, we are retaining the election policy as established in the interim final rule.

Comment: The commenter suggested that care be covered without an election under certain limited circumstances. The commenter requested a grace period of at least 72 hours to provide care for a patient in distress, or to locate a legal representative or have one appointed in the case of admitting an unresponsive or incompetent Medicare beneficiary, before fully executing the election for RNHCI care.

Response: We do not believe we have the authority for the requested grace period. The statute requires a valid election to be in place for RNHCI services to be covered and paid for. Delaying the election process is of concern particularly for an individual in distress and unable to make his or her personal wishes known.

Comment: The commenter recommended that an election be effective retroactively for care provided up to 72 hours before the election is signed. If the patient expires before the execution of a valid election, the commenter requested that Medicare pay for the care provided by the RNHCI to the beneficiary.

Response: We do not believe we have the authority to accommodate the requested pre-election coverage period.

Election Revocation § 403.724(a)(1)(iii)

Comment: The commenter indicated an inconsistency between section 1821(b)(3) of the Act and § 403.724(a)(1)(iii) of the regulation, regarding payment being received versus payment being requested. The commenter believes that the election should be revoked only if Medicare makes payment rather than when Medicare medical care is merely sought.

Response: Section 403.724(a)(1)(iii) of our regulations implements section 1821(b)(3) of the Act, which set forth the information that must be included in the election form. This section specifies that receipt of nonexcepted medical services constitutes a revocation of an election. Seeking Medicare medical care indicates that a beneficiary anticipates that the program will pay for the service under the statute. It is the payment for that Medicare claim that actually triggers the revocation of the RNHCI election and (if applicable) the start of the waiting period that determines when a new RNHCI election may be filed.

Condition of Participation: Patient Rights § 403.730(c)(4)

Comment: The commenter requested that the utilization review committee have the power to authorize the limited use of restraints when the patient poses a danger to self, other patients, or staff. The commenter indicated that since the UR committee could make an initial determination for coverage under Medicare and Medicaid, it could also be capable of determining if and when those rare occasions existed when there would be a need to protect the safety of a patient and the staff. Additionally, the commenter stated that it would be appropriate to place specific requirements on the use of restraints, such as—

- Choosing the least restrictive manner for the least amount of time as possible;
- Placing time limits for using restraints without additional review by the UR committee;
- Not permitting standing orders for the use of restraints;
- Using restraints only when absolutely necessary and other interventions have been ineffective; and
- Requiring RNHCI staff to frequently check on the restrained patient.

Response: Section 1866(ss)(1) of the Act and the related legislative history underscore the centrality of nonmedical interventions to the care provided by RNHCIs. The statute requires active patient choice and limits the benefit to those for whom the ''acceptance of medical health services would be inconsistent with their religious beliefs.'' Under this model, chemical restraints (drugs) would clearly be antithetical, as well against the statute. On the other hand, ''assistive devices'' (such as crutches, canes, and walkers, *etc.*), used only on a voluntary basis by the patient, would not constitute a ''restraint.'' We currently define ''physical restraint'' in our hospital condition of participation at § 482.13 as ''any manual method or physical or mechanical device, material, or equipment attached or adjacent to the patient's body that he or she cannot easily remove [and] that restricts freedom of movement or normal access to one's body.'' In thinking about whether a device or practice may be considered a restraint, the RNHCI

should consider how the device or practice affects the patient. For example, if a patient were in a wheelchair with a belt, the belt would not be considered a restraint if the patient can independently unsnap the belt. The key is to assess each patient and each situation to determine how a device or practice will affect the patient. If the belt described above were snapped in the back so that the patient could not reach it to release it, it would be considered a restraint. (*See* previous discussion in the preamble of the interim final at 64 FR 67032.)

Current professional standards of practice and guidelines advocate for minimal use of physical restraints, in limited medical circumstances. The Medicare and Medicaid programs have very strict criteria for the use of physical restraints in other provider types, such as hospitals and nursing homes, that require both medical supervision and intensive ''medical * * * examination, diagnosis, prognosis [and] treatment'' of the patient in order to assure that the minimum appropriate restraint is used. While it would seem that rare occasions could arise where (physical) restraints could be used to protect the safety of a patient or staff, we believe that this restraint use, without medical review poses too great a hazard. Since the RNHCI statute expressly prohibits these facilities from engaging in ''medical * * * examination, diagnosis, prognosis [and] treatment,'' the use of restraints is not within their purview.

We disagree that the utilization review committees in the RNHCIs could provide an adequate oversight function for the use of physical restraints. While the UR committees are the body responsible for ascertaining the appropriateness of Medicare (or Medicaid) covered services for an individual, they do not have the medical expertise necessary to assure that physical restraints could be provided to Medicare or Medicaid beneficiaries safely.

Condition of Participation: Food Service § 403.734(b)

Comment: The commenter requested that we add the language to our standard regarding requirements for the meal served to the patient in the RNHCI at § 403.734(b). The commenter believes we should add that the RNHCI should be required to ensure that the meals served to beneficiaries meet the recommended daily allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences, ''except insofar as compliance with such dietary allowances would be contrary to the religious beliefs observed by the institution or its personnel.'' The commenter considered the recommended dietary allowances of the National Academy of Sciences to be a medical model that involved learning the chemistry of food and determining the patient's body weight and height. As the basis for their objection, the commenter cited section 1861(ss)(3)(B)(i) of the Act, which species that the Secretary shall not subject a religious nonmedical health care institution or its personnel to any medical supervision, regulations, or control, insofar as such supervision, regulation, or control would be contrary to the religious beliefs observed by the institution or those personnel.

Response: Our first priority is to patient health and safety. We appreciate the commenter's suggestion, but we disagree with the suggested provision. We do not believe that this requirement violates section 1861(ss)(3)(B)(i) of the Act because the requirement is designed to meet general physical health needs unrelated to medical treatment for any illness, injury, or condition. Because therapeutic diets or parenteral nutrition are not expected to be ordered for the population of patients in these facilities, we are not suggesting that nurses perform duties outside the scope of their religious beliefs. The requirements in the rule are not medical in nature, but rather guidance for the maintenance of health within the general population.

Condition of Participation: Discharge Planning § 403.736(a)(1)

Comment: One commenter requested that, following the first sentence of the discharge planning evaluation standard at § 403.736(a) that states the RNCHI must assess the need for a discharge plan for patients likely to suffer adverse consequences if there is no plan and for patients upon request or at the request of their legal representative, we add the following language, ''provided that this planning process shall not require actions which would be contrary to the religious beliefs observed by the institution or its personnel.'' The commenter believes that the requirement to initiate discharge planning on admission requires the nurse to make a prognosis. Again, the commenter cited section 1861(ss)(3)(B)(i) of the Act as the basis for the objection.

Response: Again, we appreciate the commenter's suggestion for additional language, but we do not agree that the requirement violates section 1861(ss)(3)(B)(i) of the Act. The requirement for discharge planning is for the safety of the patient and does not mean that a medical prognosis is being made. The requirement is not that a prognosis be made but rather that the discharge process be started early on during a stay, and not only when discharge is imminent. The RNCHI is also responsible for identifying the qualified and experienced person for developing or supervising a discharge plan. If a patient may need additional services after discharge from the RNCHI, a plan must be in place to ensure that those services will be available in the community or another facility.

Condition of Participation: Utilization Review (UR) § 403.746(a)&(b)

Comment: The commenter objected to the requirement of having a UR plan that must contain written procedures for evaluating the duration of care and the need for continuing care of an extended duration. The commenter believes that the requirement leads to speculation about the duration of a patient's illness and requires nurses to make a prognosis, which is contrary to the nursing practice of the religious group. The commenter requested that we revise the standard under § 403.746(a) to include a disclaimer in favor of their beliefs.

Response: We are not suggesting that RNHCI nurses practice outside of their scope of practice or religious beliefs. We are requiring, however, that the RNCHI provide, through procedures written in their UR plan, the patient's initial need and appropriateness of an RNHCI stay and justifications for extending that stay. The UR condition of coverage and condition of participation are statutory, and we do not believe we have authority to alter those conditions.

Comment: The commenter requested that we remove the requirement that the governing body be included on the UR committee. The commenter stated that the governing bodies of most Christian Science facilities are made up of Christian Scientists from the large geographical area served by the facility and are not involved in the daily administration of the facility. Many do not live close enough to the facility to permit review of admissions or decisions on a daily basis. Additionally, they do not possess the skills or experience required to make appropriate UR decisions. The commenter suggested that the UR committee be composed of the administrator, superintendent of nursing, the assistant superintendent of nursing or another Christian Science nurse, and a nonvoting secretary/recorder.

Response: We appreciate the commenter's concerns; however, we do not agree with these suggestions. The purpose of this requirement is to afford

the governing body the opportunity to be involved in the daily operations of the provider. With current technology, including the governing body in the UR committee meetings may be accomplished via many avenues (for example, teleconferencing).

Comment: One commenter stated that the proposed regulations do not specify the frequency of the UR committee meeting. The organization believes that the rules before implementation of the BBA '97, which required a meeting at least every 14 days, were appropriate and should be in the new rule.

Response: We appreciate the commenter's suggestion, but we do not agree. Because there is no medical necessity for RNHCI UR committee meetings within certain time frames, we did not see a necessity to mandate these timeframes. Additionally, not mandating a timeframe for the frequency of UR committee meetings is less burdensome for the provider and can appropriately accommodate patient needs within an individual RNHCI.

C. National Fire Safety Protection Association

Condition of Participation: Life Safety From Fire § 403.744(a)(1)

Comment: The commenter commended us for our recognition of the National Fire Safety Protection Association as state-of-the-art technology in fire and life safety protection and the best method to provide continued health care fire safety to Medicare and Medicaid beneficiaries. The association applauded our reference of the 1997 edition of the Life Safety Code that, they stated, showed our commitment to Public Law 104–113, the ''National Technology Transfer and Advancement Act of 1995'' (requires Federal government agencies to use private sector, national consensus technology standards in carrying out public policy wherever appropriate).

Response: We appreciate the commenter's support. When we published the November 30, 1999 interim final rule, we required RNHCIs to comply with the 1997 edition of the Life Safe Code, which, at that time, was the latest edition. Since that time, a new regulation was published updating the Life Safety Code for providers, including RNHCIs. Therefore, we are now requiring RNHCIs to comply with the 2000 edition of the Life Safety Code that we incorporated by reference in the final rule published in the **Federal Register** on January 10, 2003 (68 FR 1374). That rule became effective on March 11, 2003.

IV. Provisions of the Final Rule

For the most part, this final rule incorporates the provisions of the November 30, 1999 interim final rule. However, we are making the following minor changes to our regulations:

- We are making editorial changes to § 403.736(a)(3) to clarify our policy regarding the discharge planning evaluation. We are specifying that the discharge planning evaluation must be included in the patient's ''care'' record rather than the patient's ''rights'' record and specified that staff are required to discuss the results of the evaluation with the beneficiary.
- We are amending to § 403.738(a) to include that RNHCIs must comply with Federal, State, and local laws pertaining to ''privacy of individually identifiable health information (45 CFR part 164).''
- We are amending the introductory text of § 489.102 to add RNHCIs among the list of providers that must maintain written policies and procedures concerning advance directives. In addition, we are adding that these advance directives must be maintained with respect to all adult individuals receiving medical care, ''or patient care in the case of a patient in a religious nonmedical health care institution.'' We intended to make these changes in the interim final rule; however, they were not incorporated due to an error in our amendatory language.
- Section 1861(ss)(i) of the Act specifies the requirements that a Medicare or Medicaid provider must meet to satisfy the definition of a RNHCI. In addition, section 1866 of the Act requires that all providers of services under Medicare enter into a provider agreement with the Secretary and comply with other requirements specified in that section. Currently, all of the 16 not-for-profit Medicare/Medicaid RNHCI providers have provider agreements with CMS. In the November 30, 1999 interim final rule, we intended to revise the regulations to include RNHCIs among the providers required to enter into provider agreements in accordance with the statute. These revisions were inadvertently omitted from the interim final rule. Therefore, in this final rule, we are revising the regulations at part 489 so that RNHCIs are subject to the requirements regarding provider agreements and supplier approval. In addition we are revising regulations at part 498 to ensure the RNHCI access to the appeals process in the case of an adverse determination concerning continued participation in the Medicare program.

Additional Change Affecting the Rule

A final rule published on January 10, 2003 (68 FR 1374) revised § 403.744 that set forth the condition of participation for life safety from fire. That final rule amended the fire safety standards for most health care providers, including RNHCIs. It adopted the 2000 edition of the Life Safety Code and eliminated references in our regulations to all earlier editions. The regulation became effective March 11, 2003. Since the rule published in January updated this provision, we are not republishing or making any additional changes to § 403.744 of the regulations.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 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 PRA 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 the issues for the provisions summarized below that contain information collection requirements:

Section 403.724 Valid Election Requirements

In summary, § 403.724(a)(1) requires an RNHCI to use a written election statement that includes the requirements set forth in this section.

The burden associated with this requirement is the one-time effort required to agree on the format for the election statement. It was estimated that it would take each RNHCI 2 hours to comply with these requirements. This was completed by the 16 RNHCIs when they started participating in the program. We know of only one provider that is considering applying to participate; thus, there will be a possible total of 2 burden hours. There have been no new applications since the first providers transitioned into the RNHCI

program. The burden associated with signing, filing, and submitting the election statement is described in § 403.724(a)(2), § 403.724(a)(3), and § 403.724(a)(4).

In summary § 403.724(a)(2) and § 403.724(a)(3) require that an election must be signed and dated by the beneficiary or his or her legal representative and have it notarized.

The burden associated with this requirement is the time required for the beneficiary or his or her legal representative to read, sign, and date the election statement and have it notarized. It is estimated that it will take each beneficiary approximately 10 minutes to read, sign, and date the election statement. We anticipate that the RNHCI will have a notary present to witness and notarize the election statement. There are approximately 800 beneficiaries that will be affected by this requirement for a total of 103.3 burden hours during the first year of the final rule.

Section 403.724(a)(4) requires that the RNHCI keep a copy of the election statement on file and submit the original to CMS with any information obtained regarding prior elections or revocations.

The burden associated with this requirement is the time required for an RNHCI to keep a copy of the election statement and submit the original to CMS. It is estimated that it will take 5 minutes to comply with this requirement. During the first year, there will be approximately 800 election statements for a total of 66.6 burden hours.

If not revoked, an election is effective for life and does not need to be completed during future admissions. Section 403.724(b)(1) states that a beneficiary can revoke his or her election statement by the receipt of nonexcepted medical treatment or the beneficiary may voluntarily revoke the election and notify CMS in writing. We anticipate that there would be very few (fewer than 10 beneficiaries) if any instances in which a beneficiary will notify CMS in writing that he or she will revoke his or her election statement. We believe the above requirement is not subject to the PRA in accordance with 5 CFR 1320.3(c)(4) since this requirement does not collect information from 10 or more entities on an annual basis.

While the information collection requirements summarized below are subject to the PRA, we believe the burden associated with these information collection requirements is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities.

Section 403.730 Condition of Participation: Patient Rights

Section 403.730(a)(1) states that the RNHCI must inform each patient of his or her rights in advance of furnishing patient care.

Section 403.730(b)(3) states that the RNHCI must formulate advance directives and expect staff who furnish care in the RNHCI to comply with those directives, in accordance with part 489, subpart I of this chapter. For purposes of conforming with the requirement in § 489.102 that there be documentation in the patient's medical records concerning advanced directives, the patient care records of a beneficiary in an RNHCI are equivalent to medical records held by other providers.

Section 403.732 Condition of Participation: Quality Assessment and Evaluation

In summary, § 403.732 states that the RNHCI must develop, implement, and maintain a quality assessment and evaluation program.

Section 403.736 Condition of Participation: Discharge Planning

Section 403.736(a)(1) requires that the discharge planning evaluation must be initiated at admission and must include the following: (1) An assessment of the possibility of a patient needing post-RNHCI services and of the availability of those services; and (2) an assessment of the probability of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the RNHCI.

Section 403.736(a)(3) states that the discharge planning evaluation must be included in the patient's care record for use in establishing an appropriate discharge plan. Staff must discuss the results of the discharge planning evaluation with the patient or a legal representative acting on his or her behalf.

Section 403.736(b)(1) states that, if the discharge planning evaluation indicates a need for a discharge plan, qualified and experienced personnel must develop or supervise the development of the plan.

Section 403.736(b)(2) states that, in the absence of a finding by the RNHCI that the beneficiary needs a discharge plan, the beneficiary or his or her legal representative may request a discharge plan. In this case, the RNHCI must develop a discharge plan for the beneficiary.

Section 403.736(b)(3) states that the RNHCI must arrange for the initial implementation of the patient's discharge plan.

Section 403.736(b)(4) states that, if there are factors that may affect continuing care needs or the appropriateness of the discharge plan, the RNHCI must reevaluate the beneficiary's discharge plan.

Section 403.736(b)(5) states that the RNHCI must inform the beneficiary or legal representative about the beneficiary's post-RNHCI care requirements.

Section 403.736(b)(6) states that the discharge plan must inform the beneficiary or his or her legal representative about the freedom to choose among providers of care when a variety of providers is available that are willing to respect the discharge preferences of the beneficiary or legal representative.

Section 403.736(c) states that the RNHCI must transfer or refer patients to appropriate facilities (including medical facilities if the beneficiary so desires) as needed for follow up or ancillary care and notify the patient of his or her right to participate in planning the transfer or referral in accordance with § ''403.730(a)(2).

Section 403.736(d) states that the RNHCI must reassess its discharge planning process on an ongoing basis. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs.

Section 403.738 Condition of Participation: Administration

In summary, § 403.738(a) states that an RNHCI must have written policies regarding its organization, services, and administration.

Section 403.738(c)(3) states that the RNHCI must furnish written notice, including the identity of each new individual or company, to CMS at the time of a change, if a change occurs in any of the following: Persons with an ownership or control interest, as defined in 42 CFR 420.201 and 455.101; the officers, directors, agents, or managing employees; the religious entity, corporation, association, or other company responsible for the management of the RNHCI; and the RNHCI's administrator or director of nonmedical nursing services.

While this information collection requirement is subject to the PRA, we believe the burden associated with this information collection requirement 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 403.742 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 RNHCIs, 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 RNHCIs 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 Willinghan, 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 RNHCIs 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

are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. For purposes of the RFA, all of the 16 not-for-profit Medicare/Medicaid RNHCI providers are considered small businesses according to the Small Business Administration's size standards, with total revenues of $6 million or less in any one year. Individuals and States are not included in the definition of a small entity.

Currently, only one religious group is participating in the RNHCI program and no other groups have applied for participation. The RNHCIs are operated as independent facilities by individual boards composed of members from the religious group. The facilities are not in competition with other medical care providers in any geographical area since they pursue a religious rather than a medical approach to health care. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities.

2. Effects on Other Health Care Providers

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 and has fewer than 100 beds. This rule will not have a significant impact on small rural hospitals. The RNHCIs are not in competition with other medical care providers in any geographical area, since they pursue a religious rather than a medical approach to health care. Currently, all of the RNHCIs are located in metropolitan rather than rural areas. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

3. Effects on States, Local or Tribal Governments

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This rule will have no consequential effect on the governments mentioned 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.

In accordance with the provisions of Executive Order 13132, this regulation will not significantly affect any State or local government. This rule describes only processes that must be undertaken if a State chooses to exercise its option to amend the State plan and include coverage of inpatient RNHCI services.

Those States that have RNHCI facilities and have selected to offer the optional RNHCI service are very limited. Currently, we only have 16 facilities participating in Medicare and one of these is dually eligible to participate in Medicare and Medicaid. The monitoring of the program is conducted by staff in the Boston Regional Office (Region I) and they will be responsible for the survey and certification activity that is usually conducted by a State Agency. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

4. Effect on the Medicare and Medicaid Programs

Section 4454 of BBA '97 removed the authorization for payment for services furnished in Christian Science sanatoria from under both Medicare and Medicaid. Section 4454 authorizes payment for inpatient services in an RNHCI for beneficiaries who, for religious reasons, are conscientiously opposed to the acceptance of medical care. Section 4454 of BBA '97 provides for coverage of the nonmedical aspects of inpatient care services in RNHCIs under Medicare and as a State option under Medicaid. In order for a provider to satisfy the definition of a religious nonmedical health care institution, for both Medicare and Medicaid, it must satisfy the 10 qualifying provisions contained in section 1861(ss)(1) of the Act. The RNHCI choosing to participate in Medicare must also be in compliance with both the conditions for coverage and the conditions of participation contained in the regulations. Neither Medicare nor Medicaid will pay for any religious aspects of care provided in these facilities. CMS has used one fiscal intermediary to handle all RNHCIs and the Boston Regional Office to monitor the process, and we plan to continue that arrangement.

Section 4454 of BBA '97 establishes certain controls on the amount of expenditures for RNHCI services in a given FFY. Section 1821(c)(2)(C) of the Act explains the operation of these controls through the use of a trigger level.

The trigger level is used to determine if Medicare payments for the current FFY need to be adjusted. If the estimated level of expenditures for an FFY exceeds the trigger level for that FFY, we are required under statute to make a proportional adjustment to payments or alternative adjustments to prevent expenditures from exceeding the trigger level.

BBA '97 precludes administrative or judicial review of adjustments that we determine are necessary to control expenditures. The trigger level is also used to activate the sunset provision, which prohibits us from accepting any new elections when estimated expenditures exceed the trigger level for 3 consecutive fiscal years. It must be noted that the trigger level has not been even closely approached since the inception of the program.

Currently, there are 16 RNHCIs that are furnishing services and receiving payment under Medicare. One of these facilities is dually eligible to participate in Medicare and Medicaid. There have been no Medicaid expenditure reports submitted by any State for several years.

5. Effects on RNHCIs

The rule enables RNHCI providers and beneficiaries the opportunity to continue to receive funding for inpatient health care service that are in keeping with their religious convictions. Additionally, the rule provides that a beneficiary will always have the option of choosing to seek conventional medical care for covered services.

C. Alternatives Considered

This final rule adheres to the statutory provisions, which in many instances were very prescriptive; however, we used every opportunity possible to consider alternative approaches as discussed below.

Elections

The statute does not prescribe when the election must be made except to specify that it must be made before receiving care. Initially, we considered the possibility of opening the election process to all eligible beneficiaries, who would wish to pursue RNHCI services, to ensure these benefits would be available when they were admitted to an RNHCI. However, some religious groups consider it acceptable to receive some medical care (for example, closed

reduction of fractures) that is considered as nonexcepted care under the RNHCI amendments to the statute and regulations. With the above cited approach to elections, we might be placing some beneficiaries in a position of having an RNHCI election revoked one or more times without ever being admitted to an RNHCI. This would subject a beneficiary to having to wait the prescribed period of time between revocation and when they could again file a viable election. Therefore, we decided it was in the beneficiary's best interest to initiate the election process at the time of admission to an RNHCI.

Payment to Providers

The statute provided flexibility for provider payment and initially we continued the new provider group under the TEFRA payment methodology to ensure a smooth transition. The new RNHCI group was already facing a number of changes when compared with their prior requirements as Christian Science sanatoria. We considered the possibility of moving swiftly to a prospective payment methodology as systems were being developed for skilled nursing facilities, home health agencies and rehabilitation hospitals. While the new methodologies were different from those under the hospital diagnosis related group (DRG), there was still a partial diagnosis based relationship to the payment system. Since the statute prohibits the use of diagnosis or other medical approaches for assessing RNHCI patients, we have decided to wait until we can conduct studies and find a methodology that is fully appropriate for the RNHCI setting.

D. Conclusion

For the above reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act. We have determined that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

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 403

Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 498

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

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

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 continues to read as follows:

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

Subpart G—Religious Nonmedical Health Care Institutions—Benefits, Conditions of Participation, and Payment

■ 2. In § 403.736, paragraph (a)(3) is revised to read as follows:

§ 403.736 Condition of participation: Discharge planning.

* * * * *

(a) *Standard: Discharge planning evaluation.* * * *

(3) The discharge planning evaluation must be included in the patient's care record for use in establishing an appropriate discharge plan. Staff must discuss the results of the discharge planning evaluation with the patient or a legal representative acting on his or her behalf.

* * * * *

■ 3. In § 403.738, paragraph (a)(4) is added to read as follows:

§ 403.738 Condition of participation: Administration.

* * * * *

(a) *Standard: Compliance with Federal, State, and local laws.* * * *

(4) Privacy of individually identifiable health information (45 CFR part 164).

* * * * *

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 1. The authority citation for part 489 continues to read as follows:

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

■ 2. In § 489.2, paragraph (b) introductory text is republished and a new paragraph (b)(9) is added to read as follows:

§ 489.2 Scope of part.

* * * * *

(b) The following providers are subject to the provisions of this part:

* * * * *

(9) Religious nonmedical health care institutions (RNHCIs).

* * * * *

■ 3. In § 489.10 paragraphs (a) and (c) are revised to read as follows:

§ 489.10 Basic requirements.

(a) Any of the providers specified in § 489.2 may request participation in Medicare. In order to be accepted, it must meet the conditions of participation or requirements (for SNFs) set forth in this section and elsewhere in this chapter. The RNHCIs must meet the conditions for coverage, conditions for participation and the requirements set forth in this section and elsewhere in this chapter.

* * * * *

(c) In order for a hospital, SNF, HHA, hospice, or RNHCI to be accepted, it must also meet the advance directives requirements specified in subpart I of this part.

* * * * *

■ 4. In § 489.53 paragraph (a) introductry text is republished and paragraph (a)(3) is revised to read as follows:

§ 489.53 Termination by CMS.

(a) *Basis for termination of agreement with any provider.* CMS may terminate the agreement with any provider if CMS finds that any of the following failings is attributable to that provider:

* * * * *

(3) It no longer meets the appropriate conditions of participation or requirements (for SNFs and NFs) set forth elsewhere in this chapter. In the case of an RNHCI no longer meets the conditions for coverage, conditions of participation and requirements set forth elsewhere in this chapter.

* * * * *

■ 5. In § 489.102, paragraph (a) introductory text is revised to read as follows:

§ 489.102 Requirements for providers.

(a) Hospitals, critical access hospitals, skilled nursing facilities, 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 must maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care, or patient care in the case of a patient in a religious nonmedical health

care institution, by or through the provider and are required to:

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PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 1. The authority citation for part 498 continues to read as follows:

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

■ 2. In § 498.2 the definition of ''provider'' is revised to read as follows:

§ 498.2 Definitions.

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Provider means a hospital, critical access hospital (CAH), skilled nursing facility (SNF), comprehensive outpatient rehabilitation facility (CORF), home health agency (HHA), hospice, or religious nonmedical health care institution (RNHCI) that has in effect an agreement to participate in Medicare, that has in effect an agreement to participate in Medicaid, or a clinic, rehabilitation agency, or public health agency that has a similar agreement but only to furnish outpatient physical therapy or outpatient speech pathology services, and prospective provider means any of the listed entities that seeks to participate in Medicare as a provider or to have any facility or organization determined to be a department of the provider or provider-based entity under § 413.65 of this chapter.

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

Dated: May 19, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare and Medicaid Services.

Dated: August 6, 2003.

Tommy G. Thompson,

Secretary.

[FR Doc. 03–29139 Filed 11–26–03; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 408

RIN 0938–AL49

[CMS–6016–F]

Medicare Program; Reduction in Medicare Part B Premiums as Additional Benefits Under Medicare+Choice Plans

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

ACTION: Final rule.

SUMMARY: This final rule revises the regulations to provide for a Medicare+Choice organization to offer a reduction in the standard Medicare Part B premium as an additional benefit under one or more Medicare+Choice (M+C) plans. The legislation specifies that the reduction to the Medicare Part B premium cannot exceed the standard Medicare Part B premium amount and cannot be applied to surcharges. Surcharges are increased premiums for late enrollment and for reenrollment. The Medicare Part B premium may be collected by a variety of methods: Paid directly to the Centers of Medicare & Medicaid Services by the beneficiary; collected as an adjustment to any Social Security, Railroad Retirement, or Civil Service Retirement benefits; paid by an employer as part of an annuity package; or, paid by the State for individuals enrolled in a qualifying State Medicaid program. This legislation applies to benefits under Medicare M+C plans offered by an M+C organization electing this option, beginning January 1, 2003. This final rule revises the regulations to set out the basic rules under section 606 of the Medicare, Medicaid, and SCHIP Benefits Improvement Protection Act of 2000 (BIPA) for adjustment and payment of the Medicare Part B premium.

EFFECTIVE DATE: The provisions of this final rule are effective December 29, 2003.

FOR FURTHER INFORMATION CONTACT: Michele Sanders, (410) 786–0808.

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I. Background

Section 606 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) amended section 1854 (f)(1) of the Social Security Act (the Act) by allowing Medicare+Choice (M+C) organizations to elect to receive a reduction in its payment under § 422.250(a)(1), 80 percent of which would be applied to reduce (or eliminate) the standard Medicare Part B premium otherwise paid by, or on behalf of, its Medicare enrollees. This was intended to make the M+C plan more attractive to Medicare beneficiaries and increase enrollment in M+C plans.

Beneficiaries must pay a premium in order to receive Supplementary Medical Insurance benefits commonly referred to as Medicare Part B. The Part B premiums are collected monthly, most commonly as deductions from the beneficiary's Social Security or other retirement benefits. They also may be paid by a third party, such as an employer or the State Medicaid program, or are paid directly by the beneficiary.

The provisions of this final rule revising part 408 to reflect the provisions of section 606 of BIPA are described in detail in section II, Provisions of the Final Rule.

II. Provisions of the Final Rule

We are making the following revisions to 42 CFR part 408 to reflect changes in the statute made in section 606 of BIPA:

We are adding a new § 408.21 entitled ''Reduction in Medicare Part B Premium as an Additional Benefit Under Medicare+Choice Plans.'' This new provision includes paragraphs treating, respectively, the basis for a reduction of Medicare Part B premiums, the administrative requirements for a Medicare Part B premium reduction,