DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 403, 412, 431, 440, 442, 456, 446, 488, and 489

[HCFA–1909–IFC]

RIN 0938–AI93

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

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

ACTION: Interim final rule with comment period.

SUMMARY: This rule deletes all references to Christian Science sanatoria and sets forth the Medicare requirements for coverage and payment of services furnished by religious nonmedical health care institutions. It also sets forth the conditions of participation that religious nonmedical health care institutions must meet before they can participate in Medicare. It sets forth the methods we will use to pay religious nonmedical health care institutions and monitor expenditures for religious nonmedical health care institution services. Additionally, the rule presents the rules governing optional coverage of religious nonmedical health care institution services by States under the Medicaid program.

DATES: *Effective date:* These regulations are effective January 31, 2000.

The incorporation by reference of the publication in this rule was approved by the Director of the Federal Register as of January 31, 2000.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 31, 2000.

ADDRESSES: Mail an original and 3 copies of written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–1909–IFC, P.O. Box 8017, Baltimore, MD 21244–9016.

If you prefer, you may deliver an original and 3 copies of your written comments to one of the following addresses:

Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201, or Room C5–09–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

For further information on ordering copies of the **Federal Register** contained in this document, see the beginning of **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT:
General Information, Medicare Coverage, and Payment Issues: Jean-Marie Moore, (410) 786–3508
Medicare Conditions of Participation: Nancy Archer, (410) 786–0596
Medicaid Issues: Linda Tavener, (410) 786–3838.

SUPPLEMENTARY INFORMATION:

Comments, Procedures, and Availability of Copies

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–1909–IFC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

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I. Introduction

Section 4454 of the Balanced Budget Act of 1997 (BBA'97), Public Law No. 105–33, enacted August 5, 1997, which amended the Social Security Act (the Act), deletes all references to Christian Science sanatoria. Section 4454 provides for coverage 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.'') While the previous provisions were specific to Christian Science sanatoria, the new amendments make it possible for institutions other than Christian Science facilities to qualify as RNHCIs and to participate in Medicare and Medicaid. The programs will only pay for nonmedical health care services furnished in RNHCIs, as defined in the law.

This interim final rule with comment period sets forth the requirements that an RNHCI must meet to participate in the Medicare or Medicaid programs. This rule permits a Medicare beneficiary to elect to receive care in an RNHCI based on his or her own religious convictions or to revoke that election if for any reason he or she decides to pursue medical care. The rule describes the process involved in making future elections. The rule sets forth conditions of participation that an RNHCI must fully meet to participate in the Medicare program. If we find that the accreditation of an RNHCI by a State, regional, or national organization provides reasonable assurances, in accordance with 42 CFR part 488, subpart A, that all of our requirements are met or exceeded, we may treat that RNHCI as meeting the conditions of participation.

The rule presents the methodologies under which we will pay RNHCIs, monitor the Medicare expenditure level for RNHCI services for any given federal fiscal year (FFY), and implement a ''sunset'' of the RNHCI benefit. Finally, the rule revises Medicaid regulations to reflect statutory changes and makes necessary nomenclature and conforming changes.

II. Background

Since the beginning of the Medicare program, the Act contained provisions authorizing payment for certain services furnished in Christian Science sanatoria. There were similar provisions authorizing payment for such services under Medicaid. Section 4454 of BBA'97 repealed the existing Medicare

and Medicaid provisions authorizing payment for services furnished in Christian Science sanatoria. Section 4454 authorizes Medicare and Medicaid payment for certain services provided in an RNHCI, as defined in the statute. Services furnished in any facility that meets the definition of an RNHCI may qualify for payment, not just those provided in Christian Science sanatoria. It should be noted that the Medicaid RNHCI provisions are optional and not an essential component of the basic Medicaid State plan. As in the past, the new provisions do not mention the use of a religious practitioner since we consider the cost of using a religious practitioner the financial responsibility of the patient.

III. Regulatory Provisions

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

We are revising part 403 (Special Programs and Projects) of the Code of Federal Regulations by adding a new subpart G, ''Religious Nonmedical Health Care Institutions-Benefits, Conditions of Participation, and Payment.''

1. Basis and Purpose (§ 403.770)

This rule implements Section 4454 of BBA'97, which amended the following sections of the Act: 1821, and 1861(e), (y) and (ss) (Medicare provisions); 1902(a) and 1908(e)(1) (Medicaid provisions); and 1122(h) and 1162 (conforming provisions).

Section 4454 of BBA'97 modified section 1861 of the Act in several ways. First, section 4454 removed the reference to Christian Science from the definition of the term ''hospital'' in section 1861(e) and substituted ''religious nonmedical health care institution.'' Section 4454 also changed the title of section 1861(y) from ''Extended Care in Christian Science Skilled Nursing Facilities'' to ''Extended Care in Religious Nonmedical Health Care Institutions'' and substituted ''religious nonmedical health care institution'' for the reference to Christian Science sanatorium in that section.

Section 4454 added new section 1861(ss) to the Act. New section 1861(ss)(1) of the Act defines the ten minimum characteristics that a facility must have to be considered an RNHCI and provides the basis for the Medicare conditions of participation described in this rule.

Section 4454 also added a new section 1821 to the Act, providing conditions for coverage of RNHCI services. New section 1821(a) and (b) of the Act addresses the requirements that the beneficiary must fulfill to qualify for coverage and payment of RNHCI services. New section 1821(c) and (d) of the Act addresses the monitoring of expenditures for RNHCI services, safeguards against excessive expenditures for those services, and the circumstances under which the RNHCI benefit created by section 4454 will ''sunset''.

Section 4454 also amends the third sentence in section 1902(a) after the phrase ''shall not apply'' by removing the phrase ''to a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientists, Boston, Massachusetts'' and inserting ''to a religious nonmedical health care institution (as defined in section 1861(ss)(1).'' Section 4454 also amends 1908(e)(1) after the phrase ''does not include'' by removing ''a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts'' and inserting ''a religious nonmedical health care institution (as defined in section 1861(ss)(1)).'' These amendments to the Act provide for RNHCI services as a State option under the Medicaid program.

2. Definitions and Terms (§ 403.702)

In the first section of subpart G we have included a ''definitions section'' to assist readers with terms or acronyms that are used in the rule. However, if a term is defined within the text of the rule, then it is not included in the definitions section. The terms and acronyms presented in the definitions section are as follows:

Election means a written statement signed by a beneficiary or the beneficiary's legal representative indicating the beneficiary's choice to receive nonmedical care or treatment for religious reasons. The term is specific to the section 4454 provisions: it is the new process by which a beneficiary elects to choose RNHCI services rather than other covered medical services.

Excepted medical care means medical care that is received involuntarily or required under Federal, State, or local laws. It is a new term specific to the provisions implementing section 4454 and is intended to identify the kinds of medical services that can be provided to a beneficiary with an election for RNHCI services without revoking the election.

FFY is the acronym for the Federal fiscal year, which is the period used in calculating budget figures for the RNHCI program.

Medical care or treatment means health care furnished by or under the direction of a licensed physician that can involve diagnosing, treating, or preventing disease and other damage to the mind and body. It may involve the use of pharmaceuticals, diet, exercise, surgical intervention, and technical procedures.

Nonexcepted medical care means medical care, other than excepted medical care, that is sought by or for a beneficiary who has elected religious nonmedical health care institution services. It is a new term specific to the provisions implementing section 4454 and is intended to define the kinds of medical services that, if received by a beneficiary who has previously elected RNHCI services, would revoke the individual's election of services.

Religious nonmedical care or religious method of healing means health care furnished under established religious tenets that prohibit conventional or unconventional medical care for the treatment of a beneficiary. It is a term specific to the provisions implementing section 4454 and defines a specific approach to health care management.

RNHCI stands for ''religious nonmedical health care institution'' (as defined in section 1861(ss)(1) of the Act).

Religious nonmedical nursing personnel means individuals who are grounded in the religious beliefs of the RNHCI, trained and experienced in the principles of nonmedical care, and formally recognized as competent in the administration of care within their religious nonmedical health care group. The term is specific to the provisions implementing section 4454 and defines a specific group of health care workers.

3. Requirements for Coverage (§ 403.720)

In order for a Medicare or Medicaid provider to meet the definition of an RNHCI, it must satisfy the ten qualifying provisions as contained in new section 1861(ss)(1) of the Act, which are simply restated in the rule. 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 are explicitly addressed in the Medicare conditions of participation, it is essential that a facility meet all ten elements to qualify as an RNHCI for both the Medicare and Medicaid programs. Section 1861(ss)(1) of the Act states that an RNHCI means an institution that:

(a) Is described in subsection (c)(3) of section 501 of the Internal Revenue Code of 1986 and is exempt from taxes under subsection (a) of that section. The inability to either gain or retain this

status will disqualify an institution from participation as an RNHCI.

(b) Is lawfully operated under all applicable Federal, State, and local laws and regulations. Federal law supersedes State and local laws unless the State and local requirements are more stringent than the Federal requirements.

(c) Furnishes only nonmedical nursing items and services to patients who choose to rely solely upon a religious method of healing and for whom the acceptance of medical services would be inconsistent with their religious beliefs. The religious component of the healing is not covered by Medicare or Medicaid.

(d) Furnishes nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of these patients. This care frequently involves: assistance with activities of daily living; assistance in moving, turning, positioning, and ambulation; meeting nutritional needs; and comfort and support measures.

(e) Furnishes nonmedical items and services to inpatients on a twenty-four hour basis.

(f) Does not furnish, on the basis of its religious beliefs, through its personnel or otherwise, medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients.

(g) Is not owned by, under common ownership with, or has an ownership interest of five percent or more in, a provider of medical treatment or services, and is not affiliated with a provider of medical treatment or services, or with an individual who has an ownership interest of five percent or more in, a provider of medical treatment or services. For purposes of this requirement, an affiliation does not exist in the circumstances described in section 1861(ss)(4)of the Act or § 403.738(c).

(h) Has in effect a utilization review plan that:

• Provides for review of admissions to the institution, of the duration of stays, of cases of continuous extended duration, and of the items and services furnished by the institution.

• Requires that the reviews be made by an appropriate committee of the institution that includes the individuals responsible for overall administration and for supervision of nursing personnel at the institution.

• Provides that records be maintained of the meetings, decisions, and actions of the committee.

• Meets other requirements as the Secretary finds necessary to establish an effective utilization review plan.

(i) Provides information the Secretary may require to implement section 1821 of the Act, including information relating to quality of care and coverage determinations.

(j) Meets other requirements the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution. These requirements are the conditions of participation in this subpart. The RNHCI must meet or exceed the conditions of participation in order to qualify as a Medicare provider. The conditions of participation will be discussed individually in section III.A.5. of this preamble. The RNHCI must also have a valid provider agreement with HCFA.

In addition to the above requirements, section 4454 of BBA'97 added section 1821 to the Act, establishing conditions of coverage for RNHCI services. 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.

When a Medicare beneficiary has an effective election on file with us but does not have a condition that would qualify for Medicare Part A inpatient hospital or post-hospital extended care services if the beneficiary were an inpatient of a hospital or a resident of an SNF that is not an RNHCI, then services furnished in a RNHCI are not covered by Medicare. A Medicare claim for services that were furnished to that beneficiary would be treated as a claim for uncovered services. If the beneficiary only needs assistance with activities of daily living, then the beneficiary's condition could not be considered as meeting the Medicare Part A requirements.

• The beneficiary must have a valid election in effect to receive RNHCI services.

A beneficiary who meets all other applicable requirements and who has in effect a valid election to receive services in an RNHCI is eligible for coverage of those services in an RNHCI.

If no valid election is filed or the election has been revoked and no new election is in effect, the beneficiary does not have Medicare coverage for services furnished in an RNHCI. Consequently, a Medicare claim for services furnished to such a beneficiary would also be treated as a claim for uncovered 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 prior to 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.

• The RNHCI must, after reasonable investigation, determine that the beneficiary has not received nonexcepted medical treatment that would have caused his or her election to be revoked. We believe that the RNHCI is in the best position to gain information from the patient about health care incidents that may have occurred since first signing an election statement that might change the election status.

Examples:

(a) During the admission interview the RNHCI became aware that the beneficiary had been in an accident in which he or she suffered lacerations and contusions and was massively confused when transferred to a local emergency room. The emergency room staff controlled the bleeding and completed repair of the lacerations and initiated a neurological assessment before the patient's religious preferences were known. This is considered excepted medical care since the patient was not mentally competent to refuse the initiation of medical care and did not voluntarily seek medical attention. Receipt of excepted care does not revoke the beneficiary's election for RNHCI services.

(b) During the admission interview the RNHCI becomes aware that the beneficiary had visited a chiropractor to gain relief from persistent back pain. This chiropractor visit is considered nonexcepted care since the beneficiary voluntarily sought Medicare covered medical care, which effectively revokes the election for RNHCI services.

If the election has been revoked, it means the beneficiary and RNHCI are responsible for the cost of services that are denied by Medicare.

4. Valid Election Requirements (§ 403.724)

The new section 1821(b) of the Act addresses the issues involved in beneficiary election of RNHCI services. None of the provisions in this section existed prior to the passage of BBA'97.

(a) General Requirements

(i) The election must be a written statement that includes the following statements:

• The beneficiary is conscientiously opposed to acceptance of nonexcepted medical treatment as defined in § 403.702. This is a statutory requirement that is restated in the rule.

• The beneficiary acknowledges that the acceptance of nonexcepted or conventional medical treatment is inconsistent with his or her sincere religious beliefs. This is a statutory requirement that is restated in the rule.

• The beneficiary acknowledges that the receipt of nonexcepted medical treatment constitutes a revocation of the election and may limit further receipt of services in an RNHCI. We believe that it is essential that the election indicate the beneficiary's understanding as to what acts on his or her part could revoke the election.

• The beneficiary acknowledges that the election may be revoked by submitting a written statement to HCFA. We believe that it is essential that the election indicate the beneficiary's understanding as to how he or she can revoke the election.

• The beneficiary acknowledges that revocation of the election will not prevent or delay access to medical services available under Medicare Part A in facilities other than RNHCIs. We believe that it is essential that the election indicate the beneficiary's understanding that at no time will he or she be denied access to Medicare Part A services.

(ii) The election must be signed and dated by the beneficiary or his or her legal representative. We believe the election for RNHCI services can only be made by a Medicare beneficiary or his or her legal representative. An election may not be made by or on behalf of an individual prior to reaching Medicare eligibility and beneficiary status. The election may not be made for an individual by a friend or family member who is not the legal representative of the beneficiary.

(iii) The election must be notarized. We are requiring that election statements be signed by the beneficiary or his or her legal representative and notarized. We believe that this is necessary to assure the identity and relationship of the parties involved and the beneficiary's understanding of the content of the election statement. An election statement may neither be predated to seek coverage and payment for services furnished prior to the date of an election nor post-dated to meet the time limitations on making a new election imposed by an earlier revocation (see § 403.724(b)). We believe that the beneficiary must be eligible to enter an election at the time the document is signed and notarized.

(iv) The RNHCI must keep a copy of the election statement on file and submit the original to HCFA with any information obtained regarding prior elections or revocations. The maintenance of a double entry system will assure the accuracy of a beneficiary's status and eligibility for RNHCI services. While we require the receipt of an original copy of the election in order to complete the filing process, there is nothing that precludes the signing of multiple originals at the same time. The provider or the beneficiary and his or her legal representative may be more comfortable in having an original rather than a copy for future reference. Having an original of the election may be particularly important to beneficiaries who feel they might relocate at some future date and may not be readmitted to the same RNHCI.

(v) The election becomes effective on the date it is signed. The dating of the election is required to establish a history that documents the beneficiary's eligibility for RNHCI services.

(vi) The election remains in effect until revoked. Since there is no time limitation on the term of the election statement, it will remain effective until revoked by the written request of the beneficiary or action of the beneficiary in seeking nonexcepted medical care as defined in § 403.702.

(b) Revocation of Election

(i) A beneficiary's election is revoked by one of the following:

• The beneficiary receives nonexcepted medical treatment for which Medicare payment is requested. Under section 1821(b)(3) of the Act, an election by a beneficiary will be revoked if the beneficiary receives nonexcepted medical treatment for which Medicare payment is sought.

Nonexcepted medical treatment in this rule refers to any medical care or treatment other than excepted medical treatment.

Examples of nonexcepted medical care could include but are not limited to the following:

+ A beneficiary receiving medical diagnosis and/or treatment for persistent headaches and/or chest pains.

+ A beneficiary in an RNHCI who is transferring to a community hospital to have radiological studies and the reduction of a fracture.

+ A beneficiary with intractable back pain receiving medical, surgical, or chiropractic services.

• Under section 1821(b)(3) of the Act, an election by an individual may also be revoked voluntarily by notifying us in writing.

(ii) The receipt of excepted medical treatment as defined in § 403.702 does not revoke the election made by a beneficiary. Examples of excepted services include but are not limited to the following:

+ A beneficiary who receives vaccinations required by a State or local jurisdiction. This is compliant behavior to meet government requirements and not considered as voluntarily seeking medical care or services.

+ A beneficiary who is involved in an accident and receives medical attention at the accident scene, or in transport to a hospital, or at the hospital before being able to make their beliefs and wishes known.

+ A beneficiary who is unconscious and receives emergency care and is hospitalized before regaining consciousness or being able to locate his or her legal representative.

(c) Limitation on Subsequent Elections

(i) If a beneficiary's election has been made and revoked twice, the following limitations on subsequent elections apply:

• The third election is not effective until 1 year after the date of the most recent revocation.

• Any succeeding elections are not effective until 5 years after the date of the most recent revocation.

Section 1821(b)(4) of the Act provides limitations on subsequent elections. An individual may file an election and revoke it twice with no affect on benefits paid under Medicare Part A for services furnished in an RNHCI. However, once an individual's election has been made and revoked twice, the next (third) election may not become effective until the date that is one year after the date of the most recent revocation. Any succeeding election (fourth or later) will not become effective until the date that is five years after the date of the most recent revocation. While there are progressive waiting periods for an individual to file an election following the second revocation, there is never a waiting period for the individual to be able to receive covered medical services as a Medicare beneficiary.

(ii) HCFA will not accept as the basis for payment of any claim any election filed on or after January 1 of the calendar year in which the sunset provision described in § 403.756 becomes effective. Section 1821(d) of the Act provides that if the sunset provision becomes effective we may not accept any more elections for RNHCI services. The sunset provision is discussed in detail in section III. A.9. and § 403.756 of this rule.

5. Conditions of Participation

(a) Patient Rights (§ 403.730)

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.

Patient health and safety cannot be protected simply by avoiding obvious risk factors such as safety hazards or inadequate staff. Therefore, patient rights dealing with freedom from physical, psychological, and verbal abuse, misappropriation of property, and physical restraints are examples of direct protections of patients' physical and emotional health and safety. Successful restoration of health depends on many factors related to emotional health, including a general feeling of well-being. We believe patient health and safety can be protected only if the RNHCI delivers patient care in an atmosphere of respect for the individual patient's comfort, dignity, and privacy. Therefore, we are setting forth a condition of participation that recognizes explicitly that the RNHCI must protect and promote certain patient rights.

The patients' rights condition at § 403.730 has four standards. The first standard requires that the RNHCI inform each patient of his or her rights before furnishing care. We are not prescribing a specific method by which a RNHCI should notify each patient of his or her rights, because we believe that each RNHCI should implement a policy that reflects its specific manner of operations and minimizes administrative burden. This standard also requires that a RNHCI have a process for prompt resolution of grievances and that it inform patients of this process. The process must include a specific person within the facility whom a patient can contact to file a grievance. In addition, the facility must provide patients with contact information for appropriate State and Federal resources.

The remaining three standards (Exercise of rights, Privacy and safety, and Confidentiality of patient records) under the patient rights condition establish a minimum set of required patient rights. In developing these provisions, we closely examined the regulations concerning patient rights for other provider types, such as nursing homes and home health agencies. Because the nature of patient care varies among provider types, we are including only those patient rights that we believe are appropriate and necessary in the religious nonmedical setting. We are requiring that a patient have the following rights:

- The right to be informed of his or her rights, to participate in the development and implementation of his or her plan of care, and to make decisions regarding his or her care.
- The right to formulate advance directives and to have those directives followed.
- The right to privacy and to receive care in a safe setting.
- The right to be free from verbal, psychological, and physical abuse, and misappropriation of property.
- The right to confidentiality of his or her care records.
- The right to be free from the use of restraints.
- The right to be free from involuntary seclusion.

We believe these patient rights are necessary in the interest of patient health and safety. We note that the rights regarding advance directives may seem superfluous for those patients seeking nonmedical care, but we believe that a patient always has the right to change his or her mind regarding the method of health care he or she chooses. Advance directives are particularly important for a patient choosing to rely solely upon a religious nonmedical method of healing as it makes his or her wishes known in the event he or she becomes incapacitated and unable to make health care choices.

HCFA policy in HCFA's nursing home interpretive guidelines defines restraints as any manual method or physical or mechanical device, material, or equipment attached to or adjacent to the patient's body that the individual cannot remove easily that restricts freedom of movement or normal access to one's own body. Physical restraints include, but are not limited to: Using bed rails to keep a patient from voluntarily getting out of bed (as opposed to enhancing mobility while in bed); tucking in a sheet so tightly that a bed bound patient cannot move; using wheelchair safety bars to prevent a patient from rising from the chair; placing a patient in a chair that prevents rising; and placing a patient in a wheelchair so close to a wall that the wall prevents the patient from rising. Bed rails may be used either as restraints or to assist in mobility and transfer of a patient only. The use of bed rails as restraints is prohibited unless they are necessary to treat a patient's medical symptoms.

Restraint use may constitute an accident hazard and professional standards of practice have eliminated the need for physical restraints except under limited medical circumstances. Potential negative outcomes for restraint use include incontinence, decreased range of motion, and decreased ability to ambulate, symptoms of withdrawal or depression, reduced social contact, and death. Studies have shown that bed rails as restraints add risk to the patient by potentially increasing the risk of more significant injury from a fall from a bed with raised rails than from a fall from a bed without bed rails. There are other, safer methods to reduce the risk of falls from a bed such as lowering the bed or putting the mattress on the floor and frequent staff monitoring. Therefore, if a cognizant, able patient requests bed rails to assist in mobility, it is not considered a restraint. If, on the other hand, a legal representative requests bed rails for a bed bound relative with no medical need for bed rails, then it is considered a restraint. The representative cannot give permission to use restraints, including bed rails for ''safety,'' if it is not necessary to treat the patient's medical symptoms. Restraining someone to keep him or her ''safe'' is limited to circumstances in which the patient has medical symptoms and a physician's order that warrant the use of a restraint (see nursing home regulations and interpretive guidelines). Since the RNHCI recognizes neither medical symptoms or physicians (and it is prohibited to do so by the Act), there is no reason that a restraint may be used in a RNHCI.

HCFA has worked for many years to reduce restraint use and is very proud of the progress it has made in doing so. Not only would allowing restraints in RNHCIs be counterproductive to their mission and niche, but it would be utterly contrary to the standards that we have developed in conjunction with other stakeholders in health care that would permit restraints only with a medical diagnosis and medical orders.

(b) Quality Assessment and Performance Improvement (§ 403.732)

We are requiring a participating RNHCI to implement a continuous effort to improve its performance, incorporating an approach that focuses on the RNHCI's efforts to improve patient care and satisfaction. Specifically, we are requiring each RNHCI to develop, implement, maintain and evaluate an effective quality assessment and performance improvement program. We are not prescribing specific methodologies to achieve this objective. Each RNHCI is free to pursue quality improvement in a manner best suited to its individual characteristics and resources. However, every RNHCI is responsible for implementing actions that result in

performance improvements across the full range of the RNHCI's services to patients. Also, we are requiring an RNHCI's quality assessment and performance improvement program to track performance to ensure that improvements are sustained over time.

The quality assessment and performance improvement condition (§ 403.732) contains two standards, the first addressing the scope of the program and the second concerning the responsibility for the program. The first standard requires that an RNHCI's quality assessment and performance improvement contain the minimum items that must be in the RNHCI's program. Specifically, we require that the RNHCI objectively evaluate the following areas that we believe are critical: access to care, patient satisfaction, staff performance, complaints and grievances, discharge planning activities, and safety issues, including physical environment. We believe that these items comprise the fundamental building blocks of a well-managed RNHCI.

Additionally, § 403.732 states that for each area listed above, and any other areas the RNHCI includes, the RNHCI must define and describe quality assessment and performance improvement activities that are appropriate for the services furnished by or in the RNHCI.

Because of the unique nature of the care furnished in RNHCIs, we are not prescribing a specific definition of quality or outlining what activities are appropriate to meet this standard. However, we welcome any comments on whether the regulations should include some prescribed methods and some definitions on the nature of quality in an RNHCI.

Additionally, the RNHCI must measure, analyze, and track performance that the RNHCI adopts or develops that reflects processes of care and RNHCI operations. By ''measure'' we mean that the RNHCI must use an objective means of tracking performance that enables the RNHCI to identify differences in performance between two points in time. For an RNHCI to consider that it is ''doing better'' is a subjective statement and is not an acceptable measure. There must be some identifiable units of measurement that a knowledgeable person can distinguish as evidence of change. Not all objective measures must be shown as valid and reliable (that is, subjected to scientific development) to be usable in improvement projects, but they will at least identify a starting point and an ending point stated in objective terms that relate to the objectives and outcomes of the improvement projects. However, rather than mandating specific performance measures, we are allowing each RNHCI the flexibility to identify its own measures of performance for the activities it identifies as priorities in its quality assessment and performance improvement strategy. We are also requiring that the RNHCI inform the patients of the scope and responsibilities of the quality assessment and performance improvement program.

We also are requiring in § 403.732 that an RNHCI set priorities for performance improvement, based on the prevalence and severity of the identified problem(s). Lastly, this standard requires the RNHCI to take action to correct problems identified through its quality assessment and performance improvement program. We envision an RNHCI meeting this requirement by conducting an analysis when adverse outcomes are identified and then taking action to enact long-term correction and improvement of the identified problems.

The second standard, Program responsibilities, requires that the RNHCI's governing body ensure that there is an effective quality assessment and performance improvement program. We are requiring that the governing body and administration officials be responsible for ensuring that the quality assessment and performance improvement program addresses identified priorities and be responsible for implementing and evaluating improvements. Additionally, the standard requires that all programs, departments, and functions be a part of the RNHCI's quality assessment and performance improvement program. This also includes any services carried out under contract.

(c) Food services (§ 403.734)

This condition has two standards. The first standard, Sanitary conditions, requires that food provided to patients be obtained, stored, prepared, distributed and served under sanitary conditions. We believe that it is necessary for any acceptable food services program to serve food that meets these criteria. The other standard requires that meals be prepared which furnish adequate nutrition based on the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences. We believe this standard is necessary to protect the health and safety of patients in an RNHCI and that the Board's guidelines can appropriately be used here because they represent accepted practices that are in widespread use in other providers. We are not requiring therapeutic diets or parenteral nutrition as these are considered medical practices.

Additionally, this standard requires that food furnished be palatable, attractive and served at the proper temperature. The RNHCI is also required to offer substitutes of similar nutritional value to patients who refuse food served or desire alternative choices. All meals are to be furnished at regular times comparable to normal mealtimes in the community and in no instance may there be more than 14 hours between a substantial evening meal and breakfast the next day. Additionally, there RNHCI must offer snacks at bedtime.

(d) Discharge Planning (§ 403.736)

Under this condition, we are requiring the RNHCI to implement a discharge planning process to assure that appropriate post-RNHCI services are obtained for each patient, as necessary. The discharge planning process will apply to services furnished by the RNHCI to ensure a timely and smooth transition to the most appropriate type of setting for the patient. To be compatible with other regulations for other providers, we are dividing the condition into several standards—Discharge planning evaluation, Discharge plan, Transfer or referral, and Reassessment.

The first standard concerns the identification of patients in need of evaluation. We are requiring an RNHCI to assess the need for a discharge plan for patients likely to suffer any adverse consequences if there is no planning and for other patients upon their request. The discharge planning process must be initiated when the patient is admitted to the facility. Additionally, we are requiring that discharge planning be initiated upon the request of the patient or a legal representative acting on his or her behalf. The discharge planning evaluation must include an assessment of the possibility of a patient needing services after discharge and the patient's capacity for self-care or care in the environment from which he or she entered the RNHCI. We are requiring that the evaluation be completed on a timely basis and included in the patient's rights record, thus ensuring that appropriate arrangements for post-RNHCI care are made before discharge and avoiding unnecessary delays. We believe these requirements are necessary because they emphasize the need for prompt action to assess and act on the discharge planning needs of the patients.

The second standard requires that qualified and experienced personnel develop the discharge plan and that the RNHCI be responsible for the implementation of the plan. We assume this plan to be thoughtful and tailored to each individual's needs. A statement such as ''the patient was discharged to XYZ facility'' is not considered a discharge plan. We assume the plan would provide recommendations and arrangements for placement, either in the community or in the environment from which the patient was admitted. The RNHCI is also responsible for reassessing each individual's plan for factors that may affect the appropriateness of the plan. The patient or the legal representative must be informed and prepared for any post-RNHCI care. Additionally, the RNHCI must inform the patient or legal representative of his or her ability to choose among any (medical facilities or otherwise) participating Medicare providers that will respect the preferences of the patient and family.

The third standard requires the RNHCI to transfer or refer patients in a timely manner to another facility (including a medical facility, if requested by the beneficiary or his or her legal representative), in accordance with § 403.730(b)(2). The RNHCI must notify the patient of his or her rights to make decisions about care, including transfers and discharges, and must involve the patient in decisions about the transfers and discharges. Furthermore, the patient always has the choice to revoke his or her election for RNHCI care (in accordance with the revocation provisions in § 403.724(b)) in order to receive care in a traditional medical setting. While we expect that all transfers and referrals will be made in a timely manner, we expect that RNHCIs will act as expeditiously as needed to implement transfers or referrals to a medical facility that are requested by a patient after the patient's revokes his or her election for RNHCI care.

The last standard requires the RNHCI to reassess its discharge planning process on an ongoing basis. This reassessment must include reviewing a sampling of discharge plans and follow-up with the patient, if necessary, to ensure that the RNHCI was responsive to his or her discharge needs.

(e) Administration (§ 403.738)

The first standard is the same as section 1861(ss)(1)(B) of the Act, which requires the RNHCI to be operated under all Federal, State, and local laws. The administration condition requires the RNHCI to have written policies regarding organization, services, and administration. This condition consists of three standards—Compliance with Federal, State, and local laws, Governing body, and Ownership and disclosure.

In addition, we are requiring that the RNHCI meet the applicable provisions of other HHS regulations, including but not limited to those pertaining to nondiscrimination on the basis of race, color or national origin (45 CFR part 80); nondiscrimination on the basis of handicap (45 CFR part 84); nondiscrimination on the basis of age (45 CFR part 91); protection of human subjects of research (45 CFR part 46); and fraud and abuse (42 CFR part 455). Although these regulations are not in themselves considered requirements under this part, their violation may result in the termination of the provider agreement or the suspension of, or the refusal to grant or continue, payment of Federal funds to an RNHCI.

The second standard, Governing body, described in § 403.738(b), requires that the RNHCI appoint a governing body, or a person designated to function as a governing body, to be responsible for establishing and implementing policies regarding the RNHCI's management and operation. We assume that the governing body will create an environment that ensures high quality care that is consistent with patient needs and the effective administration of the RNHCI.

We want to emphasize that the governing body is responsible for the entire operation of the RNHCI, including contracts, arrangements, and the appointment of an administrator. While the governing body requirements may necessitate the implementation of certain processes, we believe they are essential to ensuring that the RNHCI with which HCFA has entered into a provider agreement is, in fact, able to ensure patient health and safety. To ensure this accountability, we have specified the responsibility of the governing body for establishing and implementing all policies regarding the RNHCI's management and operation. We believe the performance of these basic organizational functions is necessary for a patient-centered environment.

The third standard states the provisions of sections 1861(ss)(1)(G)(I) and 1861(ss)(4) of the Act, which permit ownership interests and affiliations if they meet certain criteria. Under the third standard, a RNHCI may not be owned by, be under common ownership with, or have an interest in a provider of medical treatment services. Additionally, the RNHCI may not be affiliated with a provider of medical treatment or services or affiliated with an individual who has an ownership interest in a provider of medical treatment or services. Permissible affiliations are one of the following:

- An individual serving as an uncompensated director, trustee, officer, employee, or other member of the governing body of the RNHCI, or
- An individual who is a director, trustee, officer, employee, or staff member of a RNHCI having a family relationship with an individual who is affiliated with (or has an ownership interest in) a provider of medical treatment or services, or
- An individual or entity furnishing goods or services as a vendor of medical treatment to both providers of medical treatment or services and RNHCIs.

We have included the requirement that the RNHCI also comply with ownership disclosure requirements of §§ 420.206 and 455.104 of 42 CFR Chapter 4.

In order to adequately monitor the potential for fraud and abuse in the program, we have added an additional requirement that the RNHCI also furnish written notice to HCFA if a change occurs in any of the following:

- Persons with ownership or controlling interest.
- The officers, directors, agents or managing employees.
- The religious entity, corporation, association, or other company responsible for the management of the RNHCI.
- The administrator or director of nonmedical nursing services.

(f) Staffing (§ 403.740)

Under the condition for staffing we are requiring the RNHCI to have qualified experienced personnel present in sufficient numbers to meet the specific needs of the patients. The overall goal of this condition is to ensure that all the RNHCI's areas, not just those directly involved with patient care, are staffed with sufficient, qualified personnel. We believe an efficient and well-run institution is the product of all staffing areas working to improve the overall quality of the facility.

This condition is composed of three standards which support the objective that the RNHCI be staffed with qualified personnel. The first of these standards, Personnel qualifications, concerns qualifications of those individuals who furnish care to patients. We want to emphasize that the standard applies to all such individuals, whether or not they are employed or compensated by the RNHCI or, if they are compensated,

whether salaried or contractors. This standard reflects our view that the conditions of participation for RNHCIs should not prescribe specific Federal personnel requirements for nonmedical personnel or attempt to limit or specify the functions they may perform.

The next standard, Education, training, and performance evaluation, is intended to ensure that the RNHCI staff are aware of their job responsibilities and are capable of meeting them. We are requiring that personnel receive education or training needed to help them achieve this goal. This education may include training that is related to the individual job description, performance expectations, applicable organizational policies and procedures, and safety responsibilities. We are emphasizing that under this standard, the RNHCI is responsible only for ensuring that the individual adequately knows the nature of his or her specific job duties. The individual is responsible for his or her own basic education, and for any continuing education needed to retain specific certification(s), unless the RNHCI chooses to assume this responsibility as part of the staff development process.

The second part of this standard requires all personnel in the RNHCI, as well as contractors and individuals working under arrangement, to demonstrate in practice the skills and techniques necessary to perform their assigned duties and responsibilities. It is not enough that the RNHCI demonstrates that staff has received training, or indicate how much training has been offered or provided. For effective health and safety of the patients, it is critical that all staff use the skills and techniques necessary to do their jobs correctly.

Lastly, this standard requires the RNHCI to evaluate the performance of the staff and implement measures for improvement as needed. We assume that all staff, whether directly or indirectly involved in patient care, will perform their duties competently and efficiently and it is the RNHCI's responsibility to ensure that the staff meet these expectations on an ongoing basis.

(g) Physical Environment (§ 403.742)

As with other providers, we expect an RNHCI to maintain a physical environment that ensures the safety of the patients, staff, and the public. We developed the physical environment standards based upon our experiences with other providers participating in the Medicare or Medicaid program. Section 403.742 consists of two standards, Buildings and Patient rooms. We have set forth requirements that we believe are fundamental to effective management of an RNHCI's physical environment.

The first standard, Buildings, requires that the condition of the physical plant and the overall environment be developed and maintained so that the safety and well-being of the patients are ensured. These requirements state that there must be emergency power for emergency lights and for fire detection, alarm, and extinguishing systems; procedures for proper storage and disposal of trash; proper ventilation, light, and temperature control throughout the RNHCI; a written disaster plan to address loss of power, water, and sewage; facilities for emergency gas and water supply; an effective pest control program; a preventive maintenance program for essential equipment; and a working call system for patients to summon aid or assistance.

The second standard, Patient rooms, requires that all patient rooms be designed and equipped for the adequate care, comfort and privacy of the patient. We have designated that each room accommodate no more than four patients and measure at least 80 square feet per patient if a multiple patient room, and 100 square feet per patient for a single patient room. We may permit variances in the standards relating to room size on a case-by-case basis if these variances are intended for the special needs of the patients and will not adversely affect the patients' health or safety. Additionally, each room must have direct access to an exit corridor, have at least one window to the outside, and have a floor at or above grade level. Each room must be designed or equipped to ensure full visual privacy for each patient.

The rest of the patient rooms standard concerns what furnishings the RNHCI must provide each patient. The RNHCI is responsible for furnishing a separate bed of the proper size and height outfitted with a clean, comfortable mattress and bedding appropriate for the weather and climate. Functional furniture appropriate for the patient's needs must also be provided including individual closet space with clothes racks and shelves that are accessible to the patient.

(h) Life Safety From Fire (§ 403.744)

The Life Safety Code, developed by the National Fire Protection Association, serves as the basis for many Federal, State, and local fire safety regulations. The Life Safety Code is a nationally recognized standard that includes fire protection requirements necessary to protect patients in health care facilities. The Life Safety Code covers construction, fire protection, and occupancy features needed to reduce danger to life from fire, smoke and fumes. The code is applied to both new and existing buildings. The National Fire Protection Association revises the code periodically to reflect advancements in fire protection.

Under the condition we are requiring that an RNHCI comply with the 1997 edition of the Life Safety Code that we have incorporated by reference. We are adopting the 1997 edition of the code because we believe that it provides the highest available level of protection for patients, staff and the public. The regulations also provide that we may waive specific provisions of the code that would result in unreasonable hardship upon an RNHCI, if the waiver does not adversely affect patient health and safety. Additionally, the regulations permit an RNHCI to meet a fire and safety code imposed by State law if HCFA finds that the State imposed code adequately protects patients.

The balance of the condition requires that an RNHCI have written fire control plans that contain provisions for prompt reporting of fires; protection of patients, staff and the public; evacuation; and cooperation with the fire fighting authorities. Other written evidence must be maintained by the RNHCI that documents the regular inspection and approval by the State or local fire agency.

(i) Utilization Review (§ 403.746)

Section 1861(ss)(1)(H) of the Act requires an RNHCI to have in effect a utilization review plan. Each RNHCI must have in effect its own utilization review plan, including the establishment of a utilization review committee to carry out the functions of the program.

Under the first standard, we are requiring that the UR plan contain written procedures for evaluating admissions, the duration of care, the need for extended care, and the items and services furnished by the RNHCI.

The second standard provides for the establishment of a UR committee which will be responsible for all functions of the UR program. We expect the utilization review committee to be responsible for evaluating each admission to the facility to ensure that the admission is necessary and appropriate. We are requiring that the committee consist of the governing body, the administrator or other individual responsible for the administration of the RNHCI, the nursing supervisor, and other staff as

appropriate. The committee will evaluate the estimated duration of care and, in the event of an extended stay, review the necessity and appropriateness of the continued stay. We assume that the committee will establish criteria and select norms to be used in determining the necessity of admissions, extended stays and other services offered by or in the facility as well as an ongoing review of these items. If the committee cannot establish necessity or appropriateness of care, we assume that the RNHCI will recommend that the patient's admission, extended stay, or other services not be approved for payment.

Unlike other providers participating in the Medicare and Medicaid programs, RNHCIs do not offer any medical treatments or procedures, conventional or otherwise. Therefore, we do not believe it is appropriate to prescribe a specific method or form for the utilization review plan. While we have initially decided that allowing flexibility for each RNHCI in the process of development and implementation of a utilization review plan in a RNHCI will aid in more efficient and appropriate delivery of services, we welcome comments on whether a more prescriptive method should be required.

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) starting in FFY 2000. In addition, beginning with FFY 1999, section 1821(c)(3) of the Act 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.

The estimation of expenditures will take into consideration factors that could impact on this budget projection. These factors include, but are not limited, to projection of new facilities, the number of beneficiaries making elections under this provision, trends in discharges, length of stays, inflation, and other events that could affect future expenditures. As required by section 1861(e) of the Act, we will issue an annual Report to Congress, reviewed by OMB, as the vehicle for reporting potential need to make adjustments in payments and proposed mechanisms to be employed in order to stay within the established expenditure trigger level.

The first objective of the yearly estimate is to determine if payment adjustments are required during the FFY to prevent the level of estimated expenditures from exceeding the ''trigger level.'' The trigger level is defined in section 1821(c)(2)(C) of the Act as the ''unadjusted trigger level'' for an FFY increased or decreased by the carry forward from the previous FFY. Section 1821(c)(2)(C)(ii)(I) of the Act establishes the unadjusted trigger level at $20,000,000 for FFY 1998, which is also the trigger level for that year. To calculate each succeeding unadjusted trigger level for an FFY, it is necessary to adjust the unadjusted trigger level from the prior year by the average percentage increase in the consumer price index for the 12-month period ending with July preceding the beginning of the next FFY. To calculate the trigger level for the current FFY, the unadjusted trigger level (after being modified by the consumer price index for the current year) is either increased or decreased by the carry forward from the previous FFY; that is, by the amount by which expenditures for RNHCI services either exceeded or fell short of the trigger level for that previous FFY.

We believe that adhering to the terminology that appears in the statute to explain the calculation of the trigger level might be confusing because it requires an unadjusted trigger level to be adjusted twice, once by the consumer price index and once by the carry forward. Therefore, to help clarify our explanation of the calculation of the trigger level, we use a new term to identify the unadjusted trigger level from the prior FFY. The new term, ''base year amount,'' is the unadjusted trigger level from the previous FFY. To calculate the unadjusted trigger level for the current FFY, the base year amount is adjusted by the average consumer price index. This unadjusted trigger level is then increased or decreased by the carry forward to compute the trigger level for the current FFY.

To help explain the statutory provision, we have prepared the following example.

Example (1). Trigger Level Calculation. This example shows the calculation of the trigger level starting with FFY 1998. For FFY 1998, the unadjusted trigger level and the trigger level are the same. The initial unadjusted trigger level is established in the statute at $20,000,000 for FFY 1998. For FFY 1999, the base year amount is the unadjusted trigger level from the prior year, $20,000,000. The unadjusted trigger level for 1999 is $20,700,000, which is the base year amount ($20,000,000) increased by the multiplication of the base year amount by the consumer price index of 3.5 percent ($20,000,000 times .035 = $700,000). For FFY 1999 the trigger level equals the unadjusted trigger level since there is no carry forward. For FFY 2000, the base year amount is $20,700,000, which is the unadjusted trigger level from the prior year.

Fiscal year	Base year amount	CPI	Unadjusted trigger Level	Trigger level	Actual outlays	Carry forward
Column	1	2	3	4	5*	6
1998	$-0-	N/A	$20,000,000	$20,000,000	Not Required	$-0 -
1999	20,000,000	3.5%	20,700,000	20,700,000	$8,500,000	12,200,000
2000	20,700,000	3.5%	21,424,500	33,624,500	16,000,000	17,624,500
2001	21,424,500	3.5%	22,174,358	39,798,858	20,000,000	19,798,858
2002	22,174,358	3.5%	22,950,460	42,749,318	30,000,000	12,749,318
2003	22,950,460	3.5%	23,753,726	36,503,044	40,000,000	(3,496,956)
2004	23,753,726	3.5%	24,585,107	21,088,151	25,000,000**	(3,911,849)
2005	24,585,107	3.5%	25,445,585	21,533,736	25,000,000**	(3,466,264)
2006	25,445,585	3.5%	26,336,180	22,869,916	25,000,000**	(2,130,084)
2007	26,336,180	3.5%	27,257,946	25,127,862	27,000,000**	(1,872,138)

***Note:** Column 5 actual outlays are for this example only and do not represent a projection of expenditures. These numbers were created solely for this example.

**Adjustments required by section 1861(c)(2) of the Act.

Calculations:

Column 1—Base Year = Prior Year Unadjusted Trigger.

Column 2—CPI = For simplicity, this example uses 3.5% for each year.
Column 3—Unadjusted Trigger = Current base year times one plus the result of the base year times the consumer price index.
FFY 2000—$21,424,500 = $20,700,000 × 1.035 (1+ .035).
Column 4—Trigger Level = Unadjusted triggers level for the current fiscal year plus or minus the carry forward from the prior year.
FFY 2000—$33,624,500 = $21,424,500 + $12,200,000.
Column 6—Carry forward = Trigger level minus actual outlays.
FFY 2000—$17,624,500 = $33,624,500 − $16,000,000.
***Note:** For FFY 2004 adjustments in payments would be imposed to prevent estimated expenditures from exceeding the trigger level of $21,088,151.

Example (2). Trigger Level Calculation—Carry Forward. This example calculates the trigger level when the $50 million limitation on the carry forward applies. For FFY 2003, the trigger level is $62,503,044 and actual outlays were $10 million. The difference is $52,503,044, which is the potential carry forward to the next FFY. However, since this difference is greater than $50 million, the carry forward used to compute the trigger level for FFY 2004 is limited to $50 million. The trigger level for FFY 2004 is $74,585,107, which is computed by adding the unadjusted trigger level of $24,585,107 to the allowed carry forward amount of $50 million.

Fiscal year	Base year amount	CPI	Unadjusted trigger level	Trigger level	Actual outlays	Carry forward
Column	1	2	3	4	*5	6
1998	$-0-	N/A	$20,000,000	$20,000,000	Not Required	$-0 -
1999	20,000,000	3.5%	20,700,000	20,700,000	$8,500,000	12,200,000
2000	20,700,000	3.5%	21,424,500	33,624,500	10,000,000	23,624,500
2001	21,424,500	3.5%	22,174,358	45,798,858	15,000,000	30,798,858
2002	22,174,358	3.5%	22,950,460	53,749,318	15,000,000	38,749,318
2003	22,950,460	3.5%	23,753,726	62,503,044	10,000,000	**52,503,044
2004	23,753,726	3.5%	24,585,107	74,584,107	15,000,000	**59,585,107
2005	24,585,107	3.5%	25,445,585	75,445,585	20,000,000	**55,445,585
2006	25,445,585	3.5%	26,336,180	76,336,180	35,000,000	41,336,180
2007	26,336,180	3.5%	27,257,946	68,594,126	40,000,000	28,594,126

***Note:** Column 5 actual outlays are for this example only and do not represent a projection of expenditures. These numbers were created solely for this example.
** Carry forward limited to $50 million in computing subsequent fiscal years trigger level.

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. The reduction is designed to prevent the level of estimated expenditures from exceeding the trigger level for that FFY. However, if actual expenditures surpass the trigger level then the trigger level for the next FFY is decreased by the excess expenditures. Since the excess is a negative carry forward adjustment, it reduces the trigger level for the next FFY beginning with FFY 2004, as shown in Example 1.

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 rule at § 403.750 follows the statute and provides 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 three consecutive years and thus avoid having to implement the sunset provision.

We decided not to list the possible alternative adjustments in the rule. We considered establishing specific alternative adjustments in the regulation but believed this would not provide the flexibility needed to modify services and expenditures that section 1821(c)(2) of the Act requires in a changing environment. If, in any new FFY, the level of estimated expenditures were to exceed the trigger level, and we believe that the proportional adjustment alone would be inappropriate to reduce expenditures, we will consider making alternative adjustments including but not limited to: (1) Not certifying new facilities, (2) limiting Medicare payments to the number of patient stays from the prior year, (3) limiting the days for which Medicare would pay while a beneficiary was an inpatient, or (4) limiting the number of new elections that could be filed for RNHCI benefits. These alternative adjustments are only a few of the possible adjustments that we will consider imposing. We will consider making other adjustments depending on the magnitude of the adjustments required to prevent estimated expenditures from exceeding the trigger level. We will notify RNHCIs of the type or kind of adjustments that we will impose in a given FFY. This notification will take place before the start of the FFY in which the adjustments are to be effective.

7. Payment Provisions (§ 403.752)

(a) Payment to RNHCIs

Sections 1861(e) and (y)(1) of the Act grant us broad authority to construct a payment methodology for RNHCIs. The Congressional committee reports which accompanied this statutory provision reflected the intent of the enactors that we continue to pay facilities likely to qualify under this benefit on an interim basis until the regulations to implement the statute were in place, and we have

done so. The only providers that could qualify as RNHCIs at the time of enactment were Christian Science Sanatoria, and for that reason we decided to continue to pay those facilities based on the methodology under which they had previously been paid; that is, a reasonable cost methodology. We have decided to continue to pay RNHCIs under a reasonable cost methodology to insure a smooth transition to prospective payment, as described below.

We currently regulate Christian Science sanatoria under the regulations described in §§ 412.90 and 412.98. These regulations authorize payments to these facilities under the hospital prospective payment system or, if the facility was excluded from the prospective payment system, under reasonable cost principles. This final rule will formally eliminate § 412.90(c) and § 412.98, and treat all RNHCIs the same for payment purposes. We considered establishing different payment methodologies for inpatient hospital services and post-hospital extended care services furnished in RNHCIs, but have decided not to do so. Since the nonmedical component of both inpatient hospital services and post-hospital extended care services furnished in RNHCIs are similar, and there are no differentiating medical components, we believe it is appropriate to have one payment methodology for both types of services.

We will pay RNHCIs under the same reasonable cost methodology we have used for Christian Science sanatoria. Based on the historical data available to us, Christian Science sanatoria have had average lengths of stay exceeding 25 days, similar to long term care hospitals, and we anticipate that this pattern will continue. The Christian Science sanatoria have all qualified for exclusion from the hospital prospective payment system on this basis. We will 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 (Public Law 97–248).

As will be the case for most types of providers after the implementation of BBA'97, we eventually intend to pay all RNHCIs based on a prospective payment methodology. We are planning to look specifically at the SNF, home health, and rehabilitation hospital PPS systems as models for payment system development. The SNF PPS is resource-based and driven by an assessment instrument that captures both resources and functional status. The home health and rehabilitation hospital PPS also will be resource-based and driven by assessment instruments and functional status. Thus, they appear to have the features necessary to capture the resources needed to provide religious nonmedical care. One key challenge is to identify a system whose classification mechanism can be adapted to use the information available in the RNHCI setting, i.e., functional status and resource use but not diagnosis or other medical information. At this point, we are not sure how that can be achieved fully in any of these settings.

The application of a prospective payment methodology is a multi-step process, most of which is carried out by the fiscal intermediary. That process would require the RNHCI to complete an assessment instrument, for each beneficiary/patient on admission and at designated intervals, excluding all identified medical elements contained in the instrument. The assessment instrument is primarily geared to identifying patient capabilities and the need for assistance with activities of daily living and mobility. A completed copy of the assessment instrument would be transmitted to the fiscal intermediary to be read by computer and converted to a resource/payment classification. This would afford an individual RNHCI the ability to elect not to participate in the assessment instrument process for each beneficiary with the understanding that it would result in the automatic assignment of the minimum resource classification for payment purposes.

We believe a prospective payment approach would be effective in identifying RNHCI patient needs and appropriately paying for covered services to meet beneficiaries' health care needs. Details on the SNF prospective payment system were published in the **Federal Register** on May 12, 1998 (63 FR 26252). BBA '97 outlines the requirements for prospective payment systems to be developed for HHAs in section 4603 and for inpatient rehabilitation facilities in section 4421. Details on the proposed HHA prospective payment system will be published in the **Federal Register** in the near future. The proposed inpatient rehabilitation facility prospective payment system is expected to be published as a proposed rule in December of this year. We solicit the views of interested entities regarding the development of a prospective payment system for RNHCIs. We will consider these views in developing a proposal to pay RNHCIs under a prospective payment methodology.

(b) 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 are incorporating this provision into our regulations.

(c) 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) 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.

Because the statute gives us authority to impose a wide variety of alternative reductions, and because we are not specifying those alternative adjustments in the rule, we also decided not to include in the rule a formula for the computation of the amount of the Medicare reduction. Establishing a set formula in regulations also would not provide flexibility to compute the liability of a beneficiary if there was a change in the way RNHCIs are paid later. Instead of limiting the computation to a rigid set of rules, the regulations only state that RNHCIs have the right to bill beneficiaries for the amount of the Medicare reduction.

To inform beneficiaries of this liability, the regulations require RNHCIs to inform each beneficiary in writing of any proportional adjustment in effect at the time of their admission or any proportional adjustment that may become effective during the beneficiary's Medicare-covered length of stay. At least 30 days before the Medicare reduction is to take effect, RNHCIs must give written notification to beneficiaries who are already receiving care. The notification includes an explanation that the law permits the RNHCI to bill beneficiaries the amount of the allowed Medicare reduction. When the RNHCI bills the beneficiary, the regulations require the RNHCI to furnish a calculation of the Medicare reduction.

If we are required to reduce payments to RNHCIs for an FFY, we will notify RNHCIs of the amount of the required payment reduction. This notification will explain how RNHCIs will calculate the additional amount that they may bill the beneficiaries.

Unless there is an unexpected growth in services furnished by RNHCIs, we do

not anticipate the need to reduce payments in the near future. However, we are using example 3 in section L below to show the potential effects on the financial liability of a Medicare beneficiary. This example assumes a proportional payment reduction of 12 percent to prevent the level of estimated expenditures from exceeding the trigger level. Because payments are required to be reduced by 12 percent (in this example), the statute permits RNHCIs to bill beneficiaries the amount of the Medicare reduction. To calculate the additional amount billable to the beneficiary in this example we would instruct RNHCIs to use the cost per diem from their most recently filed Medicare cost report multiplied by the number of days included in the individual's Medicare covered length of stay. This cost per discharge would then be reduced by any coinsurance and deductible amounts billable to the individual and any amounts billable to a third party payer. This net amount would be multiplied by the proportional adjustment required for the FFY. The result is the Medicare reduction amount that the RNHCI may bill the beneficiary. If, in this example, the cost of furnishing a covered inpatient service was $5,000 (25 days times $200 per day), the RNHCIs could bill the individual an additional $508 ($5,000—$764 × 12%). The $508 was computed by subtracting from the cost of the stay ($5,000) a deductible of $764 and any coinsurance amount ($0 in this example) times the proportional adjustment to payment of 12%. The RNHCI could bill the individual $1,272, which consists of the deductible of $764 and the amount of the Medicare reduction attributable to the beneficiary, $508.

8. Monitoring Expenditure Level (§ 403.754)

Section 1821(c)(3)(A) of the Act requires us to monitor the expenditure level of RNHCIs beginning with FFY 1999. The regulation follows the requirements of the statute and requires us to track actual Medicare expenditures for services furnished in RNHCIs. The purpose of monitoring Medicare expenditure levels is to calculate the carry forward adjustment to the trigger level required by § 403.750(d).

The carry forward adjustment is defined in section 1821(c)(3)(B)(I) of the Act and is the difference between actual expenditures and the trigger level for the prior FFY. When the level of Medicare expenditures for an FFY exceeds or is less than the trigger level for that FFY, then the trigger level for the next FFY will be reduced or increased by the amount of the excess or deficit in expenditures. However, the carry forward may not exceed $50 million for any FFY, in accordance with section 1861(c)(3)(B)(ii) of the Act.

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, beginning in FFY 2002. Under the sunset provision, only those individuals with a valid election in effect before January 1 following the end of the third consecutive FFY in which expenditures exceed the trigger level can have benefits paid under part 403, subpart G. After that date, we will not accept any elections to pay for services furnished in RNHCIs. The earliest the sunset provision could become effective is January 1, 2005. Under this scenario, only Medicare beneficiaries with a valid election in effect before January 1, 2005, could have religious nonmedical health care benefits paid by Medicare, and payment could be made only for RNHCI services provided during those elections.

We will 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.

The following example shows when adjustments are made and when the sunset provision is activated.

Example (3). This example compares the trigger level to the level of estimated expenditures to determine if adjustment in payments or alternative adjustments are required. In addition, it tracks the trigger level and the level of estimated expenditures to determine if the sunset provision is activated. For the sunset provision to become effective, estimated expenditures must exceed the trigger level for three consecutive FFYs. In FFY 2001, this example presumes that estimated expenditures for Medicare would exceed the trigger level. To prevent estimated expenditures from exceeding the trigger level, we would need to adjust payments to RNHCIs in the next FFY. This example also assumes that estimated expenditures starting in FFY 2003 will exceed the trigger level for three consecutive FFYs. In this circumstance, the sunset provision would be activated, and, therefore, no elections would be accepted after December 31, 2005. Individuals with elections in effect on or before December 31, 2005, would continue to have benefits paid under this provision for services provided for the duration of those elections.

Fiscal Year	Trigger Level	Estimated Expenditures	Adjustments in Payments
Column	1	2	3
1998	20,000,000		
1999	20,700,000		
2000	33,624,500	20,000,000	NONE REQUIRED.
2001	39,798,858	45,000,000	REDUCE PAYMENTS.
2002	42,749,318	40,000,000	NONE REQUIRED.
2003	36,503,044	45,000,000 (1 yr.)	REDUCE PAYMENTS.
2004	21,088,151	30,000,000 (2 yr.)	REDUCE PAYMENTS.
2005	21,533,736	25,000,000 (3 yr.)	REDUCE PAYMENTS.
2006	22,869,916	28,000,000	REDUCE PAYMENTS.

Note: Expenditures in this table are an example only and do not represent projection of expenditures. These numbers were created solely for this example.

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)(22) of the Act. This section permits the inclusion of any other medical care and any other type of remedial care and any other type of remedial care recognized under State law, specified by HCFA. Federal financial participation is only

available to a State for these services if they are included in the State Plan.

Prior to passage of the Balanced Budget Act of 1997, the Medicaid program reimbursed for services provided in Christian Science sanitoria, or by Christian Science nurses. The Social Security Act exempted Christian Science sanitoria from the requirements of section 1902(a)(9)(A)(State responsibility for establishing and maintaining health standards for private or public institutions in which recipients of Medicaid may receive care or services), 1902(a)(31)(requirements for plans of care, on-site inspections and evaluations of care by professional, independent review teams and subsequent reporting to the State agency by these teams concerning patients receiving care in intermediate care facilities for the mentally retarded) and 1902(a)(33) of the Act (condition of participation reviews). The statute also exempted Christian Science sanitoria from the utilization review requirements of section 1903(I)(4) of the Act and from the requirements applicable to the licensing of nursing home administrators specified in section 1908(e)(1) of the Act.

The Balanced Budget Act amended these sections of the statute to delete the references to Christian Science sanitoria and to substitute references to RNHCIs, as defined in section 1861(ss)(1) of the Act. We are incorporating these revisions into the regulations. Consequently, there is no longer authority for inclusion of Christian Science sanitoria as a coverage category in Medicaid regulations. Section 4454(b) of the BBA'97 now 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). We are therefore removing § 440.170(c), Services in Christian Science sanitoriums. Additionally, a RNHCI as defined in section 1861(ss)(1) of the Act furnishes exclusively inpatient services. Consequently, we are removing § 440.170(b), Services of Christian Science nurses, since it deals with care in the home setting. These sections are being replaced with a new § 440.170(b), which defines a RNHCI for Medicaid coverage purposes as one which meets the requirements of section 1861(ss)(1) of the Act, and a new § 440.170(c), which describes the specific ownership and affiliation requirements applicable to Medicaid RNHCIs.

In order to be eligible to bill the Medicaid program, we are requiring that a RNHCI meet the Medicare conditions of participation described in part 403 of this rule. Section 4454(b) of the BBA'97 provides for Medicaid coverage of RNHCIs as defined in section 1861(ss)(1). Section 1861(ss)(1)(J) requires that a RNHCI meet such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution. This statutory requirement is implemented for the Medicare program by the conditions of participation, which set quality and safety standards for RNHCIs. We believe that Congress' intent in incorporating section 1861(ss)(1)(J) in the Medicaid definition of a RNHCI was to ensure the inclusion of similar health and safety requirements in the Medicaid regulations. Based on our experience with Christian Science sanitoria, we expect that the majority of RNHCIs which will serve Medicaid beneficiaries will also serve Medicare beneficiaries.

Therefore, rather than developing separate Medicaid requirements, we are specifying that RNHCIs must meet the Medicare conditions of participation in order to receive Medicaid reimbursement.

C. Part 488 Survey, Certification and Enforcement Procedures

Section 1861(ss)(2) 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, we are amending the regulations at § 488.2 to add section 1861(ss)(2) 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—Provider Agreements and Supplier Approval

Technical Change

Section 4641 of the Balanced Budget Act of 1997 requires that the patient's advance directive be placed in a ''prominent part'' of his or her medical record. Therefore, we are adding ''prominent part'' to § 489.102(a)(2) to reflect this requirement; that is, providers are required to ''Document in a prominent part of the individual's current medical record * * * an advance directive.''

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the 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:

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

We are, however, requesting an emergency review of this interim final rule with comment period. In compliance with section 3506(c)(2)(A) of the PRA, we are submitting to OMB the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320, to ensure compliance with section 4454 of BBA'97. This section requires that a Medicare beneficiary (or his or her legal representative) who is entering, or who is already in, an RNHCI file an election statement 30 days after the publication of this rule in order to meet the requirements of the rule. We cannot reasonably comply with normal clearance procedures because public harm is likely to result if the agency cannot enforce the requirements of this section 4454 of BBA'97 in order to ensure that the Medicare beneficiary receives covered services in an RNHCI.

HCFA is requesting OMB review and approval of this collection 11 working days after the publication of this rule, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below within 10 working days after the publication of this rule.

During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

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 utilize 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 is estimated that it will take each RNHCI 2 hours to comply with these requirements. There are currently 19 Christian Science sanatoria participating in Medicare that are expected to apply as RNHCIs; thus, there will be a total of 38 burden hours. The burden associated with signing, filing and submitting the election statement is described in §§ 403.724(a)(2)and(3) and 403.724(a)(4).

In summary, § 403.724(a)(2) and (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 1,000 beneficiaries that will be affected by this requirement for a total of 167 burden hours during the first year.

Section 403.724(a)(4) requires that the RNHCI keep a copy of the election statement on file and submit the original to HCFA 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 HCFA. It is estimated that it will take 5 minutes to comply with this requirement. During the first year there will be approximately 1,000 election statements for a total of 84 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 nonaccepted medical treatment or the beneficiary may voluntarily revoke the election and notify HCFA in writing. We anticipate that there would be very few (fewer than 10 beneficiaries) if any instances in which a beneficiary will notify HCFA 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 ten or more entities on an annual basis.

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.

The burden associated with this requirement is the time and effort necessary to disclose the notice requirements referenced above to each patient. We estimate that on average it will take each of the 19 estimated RNHCIs 8 hours to develop the required notice and that it will take each RNHCI 5 minutes to provide each notice, with an average of 109 notices provided per RNHCI on an annual basis. Therefore, the total annual burden associated with this requirement is 173 hours after the first year. For the first year there will be an additional one-time burden of 152 hours.

In its resolution of the grievance, a RNHCI must provide the patient with written notice of its decision that contains the name of the RNHCI contact person, the process of the facility in resolving the grievance, and contact information for appropriate State and Federal resources.

The burden associated with this requirement is the time and effort necessary to disclose the written notice to each patient who filed a grievance. We estimate that on average it will take each RNHCI 15 minutes to develop and disseminate the required notice. We further estimate that 19 RNHCIs will provide 5 notices on an annual basis, a total annual burden of 1.5 hours, with an additional one-time burden of 5 hours the first year.

Section 403.736 Condition of Participation: Discharge Planning

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

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 rights record for use in establishing an appropriate discharge plan and must discuss the results of the 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

While the information collection requirement (ICR) summarized below is subject to the PRA, we believe the

burden associated with this ICR is exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

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

While the following ICR is an information collection requirement, we believe the ICR is exempt from the PRA 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 403.738(c)(4) states that the RNHCI must furnish written notice, including the identity of each new individual or company, to HCFA 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.

Section 403.742 Condition of Participation: Physical Environment

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

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 403.744 Condition of Participation: Life Safety From Fire

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

Section 403.744(a)(2) states that the RNHCI must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, staff and the public; evacuation; and cooperation with fire fighting authorities.

Section 403.744(a)(3) states that the RNHCI must maintain written evidence of regular inspection and approval by State or local fire control agencies.

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.

Drafting a utilization review plan will take each current RNHCI 3 hours, for a total one time burden of 57 hours. Though we have received no inquiries from any entity about becoming a RNHCI, for purposes of this paperwork collection requirement, we estimate that there will be one additional RNHCI each year, which will create a 3 hour burden annually.

Section 403.752 Payment Provisions

The following section describes the burden associated with the payment provisions and is subject to the PRA.

Based on the most recent data available, Medicare expenditures for Christian Science sanatoria were approximately $8 million annually. The trigger level for FFY 1998, the first year of RNHCI implementation, is $20 million. Beginning in FFY 2000, when estimated expenditures for RNHCI services exceed the trigger level for a FFY, HCFA must adjust the RNHCI payment rates.

However, because of the amount of the gap between current expenditures and the trigger level, and because we do not anticipate that the number of RNHCIs will increase significantly, we do not anticipate having to adjust the payment rates for a minimum of 3 years. Thus, the section will not be implemented and there will be no paperwork burden associated with it for several years. Therefore, there is no burden associated with the following section at this time.

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).

Section 440.170 General Provisions—Medicaid

We believe the following paperwork burden is not subject to the Act, as defined 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(b)(9) states that an RNHCI must provide information HCFA may require, upon request, 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 0938–610 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 any of these information collection and record

keeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: Julie Brown HCFA–1909–IFC, Fax number: (410) 786–0262 and,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503.

V. Regulatory Impact Analysis

We have examined the impacts of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96–354). 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 annually).

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 $5 million or less annually. Individuals and States are not included in the definition of a small entity.

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 50 beds.

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 an annual expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million.

In accordance with the provisions of Executive Order 13132, this regulation will not significantly affect the States beyond what is required by basic State Plans for Medicaid. It follows the intent and letter of the law and does not usurp State authority beyond the basic Medicaid requirements. This regulation describes only processes that must be undertaken if a State exercises its option to amend the State plan to include coverage of inpatient religious nonmedical health care institutions (RNHCIs) as set forth in section 4454 of the BBA'97.

Those States that have RNHCI facilities and have selected to offer the optional RNHCI service are very limited. At the moment we only have 18 facilities participating in Medicare and four in 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 the State Agency.

Section 4454 of the BBA'97 amended the Act to remove the authorization for payment for services furnished in Christian Science sanatoria from both Medicare and Medicaid law. Section 4454 authorizes payment for inpatient services in a 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 ten qualifying provisions contained in new 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 new regulation. Neither Medicare nor Medicaid will pay for any religious aspects of care provided in these facilities. HCFA has used one fiscal intermediary to handle all Christian Science sanatoria and the Boston Regional Office to monitor the process, and we plan to continue that arrangement for RNHCIs.

Currently, there are 19 Christian Science sanatoria that are furnishing services and receiving payment under Medicare. Three of these facilities are dually eligible to participate in Medicare and Medicaid, and there are two that only participate in Medicaid. Medicare expenditure levels for Christian Science sanatoria has been approximately $8 million annually.

We anticipate that most if not all existing Christian Science sanatoria will be certified as RNHCIs but do not know how many other facilities will be eligible to apply for participation. Therefore, we cannot project the impact this regulation will have on payments or the number of organizations that will elect to furnish services to what we believe is a very small beneficiary population.

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) explains the operation of these controls through the use of a trigger level. The trigger level for FFY 1998 is $20 million. Thereafter, this amount is increased each FFY by the average consumer price index. This amount is further increased or decreased by a carry forward amount, which is the difference between the previous FFY's expenditures and the previous FFY's trigger level.

The trigger level is used to determine if Medicare payments for the current FFY need to be adjusted. Beginning with fiscal year 2000, if the estimated level of expenditures for a FFY exceeds the trigger level for that FFY, we are required by law 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 three consecutive fiscal years.

Since the Congress has established controls over the amount of money that can be spent for RNHCI services and because Christian Science sanatoria that qualify as RNHCIs will continue to be paid on a reasonable cost basis, there should be no adverse impact on beneficiaries or on existing facilities within the next five years unless there is a dramatic increase in the number of RNHCIs and their Medicare/Medicaid patients.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act. We have determined, and we certify, 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.

IV. Regulatory Impact Statement

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all health care providers are considered to be small entities. Individuals and States are not included in the definition of a small entity.

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 50 beds.

Section 4454 of the BBA'97 amended the Act to remove the authorization for payment for services furnished in Christian Science sanatoria from both Medicare and Medicaid law. Section 4454 authorizes payment for inpatient services in a 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 ten qualifying provisions contained in new 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 new regulation. Neither Medicare nor Medicaid will pay for any religious aspects of care provided in these facilities. HCFA has used one fiscal intermediary to handle all Christian Science sanatoria and the Boston Regional Office to monitor the process, and we plan to continue that arrangement for RNHCIs.

Currently, there are 19 Christian Science sanatoria that are furnishing services and receiving payment under Medicare. Three of these facilities are dually eligible to participate in Medicare and Medicaid, and there are two that only participate in Medicaid. Medicare expenditure levels for Christian Science sanatoria has been approximately $8 million annually.

We anticipate that most if not all existing Christian Science sanatoria will be certified as RNHCIs but do not know how many other facilities will be eligible to apply for participation. Therefore, we cannot project the impact this regulation will have on payments or the number of organizations that will elect to furnish services to what we believe is a very small beneficiary population.

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) explains the operation of these controls through the use of a trigger level. The trigger level for FFY 1998 is $20 million. Thereafter, this amount is increased each FFY by the average consumer price index. This amount is further increased or decreased by a carry forward amount, which is the difference between the previous FFY's expenditures and the previous FFY's trigger level.

The trigger level is used to determine if Medicare payments for the current FFY need to be adjusted. Beginning with fiscal year 2000, if the estimated level of expenditures for a FFY exceeds the trigger level for that FFY, we are required by law 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 three consecutive fiscal years.

Since the Congress has established controls over the amount of money that can be spent for RNHCI services and because Christian Science sanatoria that qualify as RNHCIs will continue to be paid on a reasonable cost basis, there should be no adverse impact on beneficiaries or on existing facilities within the next five years unless there is a dramatic increase in the number of RNHCIs and their Medicare/Medicaid patients.

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, 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.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), agencies are required to provide a 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the 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:

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

We are, however, requesting an emergency review of this interim final rule with comment period. In compliance with section 3506(c)(2)(A) of the PRA, we are submitting to OMB the following requirements for emergency review. We are requesting an emergency review because the collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR part 1320, to ensure compliance with section 4454 of BBA'97. This section requires that a Medicare beneficiary (or his or her legal representative) who is entering, or who is already in, an RNHCI file an election statement 30 days after the publication of this rule in order to meet the requirements of the rule. We cannot reasonably comply with normal clearance procedures because public harm is likely to result if the agency cannot enforce the requirements of this section 4454 of BBA'97 in order to ensure that the Medicare beneficiary receives covered services in an RNHCI.

HCFA is requesting OMB review and approval of this collection 11 working days after the publication of this rule, with a 180-day approval period. Written comments and recommendations will be accepted from the public if received by the individuals designated below within 10 working days after the publication of this rule.

During this 180-day period, we will publish a separate **Federal Register** notice announcing the initiation of an extensive 60-day agency review and public comment period on these requirements. We will submit the requirements for OMB review and an extension of this emergency approval.

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 utilize 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 is estimated that it will take each RNHCI 2 hours to comply with these requirements. There are currently 19 Christian Science sanatoria participating in Medicare that are expected to apply as RNHCIs; thus, there will be a total of 38 burden hours. The burden associated with signing, filing and submitting the election statement is described in §§ 403.724(a)(2) and (3) and 403.724(a)(4).

In summary, § 403.724(a)(2) and (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 1,000 beneficiaries that will be affected by this requirement for a total of 167 burden hours during the first year.

Section 403.724(a)(4) requires that the RNHCI keep a copy of the election statement on file and submit the original to HCFA 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 HCFA. It is estimated that it will take 5 minutes to comply with this requirement. During the first year there will be approximately 1,000 election statements for a total of 84 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 HCFA in writing. We anticipate that there would be very few (fewer than 10 beneficiaries) if any instances in which a beneficiary will notify HCFA 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 ten or more entities on an annual basis.

While the information collection requirements (ICR) summarized below are subject to the PRA, we believe the burden associated with these ICRs 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 403.732 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 rights record for use in establishing an appropriate discharge plan and must discuss the results of the 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 states that an RNHCI must have written policies regarding its organization, services, and administration.

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 403.744 Condition of Participation: Life Safety From Fire

Section 403.744(a)(2) states that the RNHCI must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, staff and the public; evacuation; and cooperation with fire fighting authorities.

Section 403.744(a)(3) states that the RNHCI must maintain written evidence

of regular inspection and approval by State or local fire control agencies.

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.

Section 489.102 Requirements for Providers

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.

While the following ICR 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 403.738 Condition of Participation: Administration

Section 403.738(c)(4) states that the RNHCI must furnish written notice, including the identity of each new individual or company, to HCFA 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.

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 $8 million annually. The trigger level for FFY 1998, the first year of RNHCI implementation, is $20 million. Beginning in FFY 2000, when estimated expenditures for RNHCI services exceed the trigger level for a FFY, HCFA 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 the following ICR is not subject to the Act, as defined 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 information HCFA may require, upon request, to implement section 1821 of the Act, including information relating to quality of care coverage and determinations.

PRA Summary of Burden

The table below indicates the annual number of responses for each regulation section in this rule containing ICRs, the average burden per response in minutes or hours, and the total annual burden hours.

ESTIMATED ANNUAL BURDEN

CFR section	Responses	Average burden per response	Burden hours
403.724(a)(1)	19	2 hours	38 hours.
403.724(a)(2)(3)	1,000	10 minutes	167 hours.
403.724(a)(4)	1,000	5 minutes	84 hours.
Total			289 hours.

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 any of these information collection and record keeping requirements, please mail copies directly to the following:

Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: Louis Blank HCFA–1909–IFC, Fax number: (410) 786–0262 and,

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn.: Allison Herron Eydt, HCFA Desk Officer, Fax numbers: (202) 395–6974 or (202) 395–5167

VI. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite prior public comment on proposed rules. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

Section 4454 of BBA'97 requires us to publish this rule in final with a comment period and bypass the normal notice-and-comment period.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a

60-day comment period for public comment.

VII. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, 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, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects

42 CFR Part 403

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

42 CFR Part 412

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

42 CFR Part 431

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

42 CFR Part 440

Grant programs-health, Medicaid.

42 CFR Part 442

Grant programs-health, Health facilities, Health professions, Medicaid, Nursing homes, Reporting and recordkeeping requirements.

42 CFR Part 456

Administrative practice and procedure, Grant programs-health, Health facilities, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 466

Grant programs-health, Health facilities, Reporting and recordkeeping requirements.

42 CFR Part 488

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

Accordingly, 42 CFR chapter IV is amended as follows:

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).

2. Subpart F is added and reserved.

3. Subpart G is added to read as follows:

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

Sec.

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

§ 403.700 Basis and purpose.

This subpart implements sections 1821; 1861(e),(y), and (ss); 1869; and 1878 of the Act regarding Medicare payment for inpatient hospital or posthospital extended care services furnished to eligible beneficiaries in religious nonmedical health care institutions.

§ 403.702 Definitions and terms.

For purposes of this subpart, the following definitions and terms apply:

Election means a written statement signed by the beneficiary or the beneficiary's legal representative indicating the beneficiary's choice to receive nonmedical care or treatment for religious reasons.

Excepted medical care means medical care that is received involuntarily or required under Federal, State, or local laws.

FFY stands for Federal fiscal year.

Medical care or treatment means health care furnished by or under the direction of a licensed physician that can involve diagnosing, treating, or preventing disease and other damage to the mind and body. It may involve the use of pharmaceuticals, diet, exercise, surgical intervention, and technical procedures.

Nonexcepted medical care means medical care (other than excepted medical care) that is sought by or for a beneficiary who has elected religious nonmedical health care institution services.

Religious nonmedical care or religious method of healing means health care furnished under established religious tenets that prohibit conventional or unconventional medical care for the treatment of a beneficiary, and the sole reliance on these religious tenets to fulfill a beneficiary's total health care needs.

RNHCI stands for ''religious nonmedical health care institution,'' as defined in section 1861(ss)(1) of the Act.

Religious nonmedical nursing personnel means individuals who are grounded in the religious beliefs of the RNHCI, trained and experienced in the principles of nonmedical care, and formally recognized as competent in the administration of care within their religious nonmedical health care group.

§ 403.720 Conditions for coverage.

Medicare covers services furnished in an RNHCI if the following conditions are met:

(a) The provider meets the definition of an RNHCI as defined in section 1861(ss)(1) of the Act. That is, it is an institution that:

(1) Is described in section 501(c)(3) of the Internal Revenue Code of 1986 and is exempt from taxes under section 501(a).

(2) Is lawfully operated under all applicable Federal, State, and local laws and regulations.

(3) Furnishes only nonmedical nursing items and services to beneficiaries who choose to rely solely upon a religious method of healing and for whom the acceptance of medical services would be inconsistent with their religious beliefs.

(4) Furnishes nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of nonmedical patients.

(5) Furnishes nonmedical items and services to inpatients on a 24-hour basis.

(6) Does not furnish, on the basis of religious beliefs, through its personnel or otherwise medical items and services

(including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients.

(7) Is not owned by, is not under common ownership with, or does not have an ownership interest of 5 percent or more in, a provider of medical treatment or services and is not affiliated with a provider of medical treatment or services or with an individual who has an ownership interest of 5 percent or more in, a provider of medical treatment or services. (Permissible affiliations are described at § 403.738(c).)

(8) Has in effect a utilization review plan that sets forth the following:

(i) Provides for review of the admissions to the institution, the duration of stays, and the need for continuous extended duration of stays in the institution, and the items and services furnished by the institution.

(ii) Requires that reviews be made by an appropriate committee of the institution that included the individuals responsible for overall administration and for supervision of nursing personnel at the institution.

(iii) Provides that records be maintained of the meetings, decisions, and actions of the review committee.

(iv) Meets other requirements as the Secretary finds necessary to establish an effective utilization review plan.

(9) Provides information HCFA may require to implement section 1821 of the Act, including information relating to quality of care and coverage decisions.

(10) Meets other requirements HCFA finds necessary in the interest of the health and safety of the patients who receive services in the institution. These requirements are the conditions of participation in this subpart.

(b) The provider meets the conditions of participation cited in §§ 403.730 through 403.746. (A provider may be deemed to meet conditions of participation in accordance with part 488 of this chapter.)

(c) The provider has a valid provider agreement as a hospital with HCFA in accordance with part 489 of this chapter and for payment purposes is classified as an extended care hospital.

(d) The beneficiary has a condition that would make him or her eligible to receive services covered under Medicare Part A as an inpatient in a hospital or SNF.

(e) The beneficiary has a valid election as described in § 403.724 in effect for Medicare covered services furnished in an RNHCI.

§ 403.724 Valid election requirements.

(a) *General requirements.* An election statement must be made by the Medicare beneficiary or his or her legal representative.

(1) The election must be a written statement that must include the following statements:

(i) The beneficiary is conscientiously opposed to acceptance of nonexcepted medical treatment.

(ii) The beneficiary acknowledges that the acceptance of nonexcepted medical treatment is inconsistent with his or her sincere religious beliefs.

(iii) The beneficiary acknowledges that the receipt of nonexcepted medical treatment constitutes a revocation of the election and may limit further receipt of services in an RNHCI.

(iv) The beneficiary acknowledges that the election may be revoked by submitting a written statement to HCFA.

(v) The beneficiary acknowledges that revocation of the election will not prevent or delay access to medical services available under Medicare Part A in facilities other than RNHCIs.

(2) The election must be signed and dated by the beneficiary or his or her legal representative.

(3) The election must be notarized.

(4) The RNHCI must keep a copy of the election statement on file and submit the original to HCFA with any information obtained regarding prior elections or revocations.

(5) The election becomes effective on the date it is signed.

(6) The election remains in effect until revoked.

(b) *Revocation of election.* (1) A beneficiary's election is revoked by one of the following:

(i) The beneficiary receives nonexcepted medical treatment for which Medicare payment is requested.

(ii) The beneficiary voluntarily revokes the election and notifies HCFA in writing.

(2) The receipt of excepted medical treatment as defined in § 403.702 does not revoke the election made by a beneficiary.

(c) *Limitation on subsequent elections.* (1) If a beneficiary's election has been made and revoked twice, the following limitations on subsequent elections apply:

(i) The third election is not effective until 1 year after the date of the most recent revocation.

(ii) Any succeeding elections are not effective until 5 years after the date of the most recent revocation.

(2) HCFA will not accept as the basis for payment of any claim any elections executed on or after January 1 of the calendar year in which the sunset provision described in § 403.756 becomes effective.

§ 403.730 Condition of participation: Patient rights.

An RNHCI must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* The RNHCI must do the following:

(1) Inform each patient of his or her rights in advance of furnishing patient care.

(2) Have a process for prompt resolution of grievances, including a specific person within the facility whom a patient may contact to file a grievance. In addition, the facility must provide patients with information about the facility's process as well as with contact information for appropriate State and Federal resources.

(b) *Standard: Exercise of rights.* The patient has the right to:

(1) Be informed of his or her rights and to participate in the development and implementation of his or her plan of care.

(2) Make decisions regarding his or her care, including transfer and discharge from the RNHCI. (See § 403.736 for discharge and transfer requirements.)

(3) 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.

(c) *Standard: Privacy and safety.* The patient has the right to the following:

(1) Personal privacy.

(2) Care in a safe setting.

(3) Freedom from verbal, psychological, and physical abuse, and misappropriation of property.

(4) Freedom from the use of restraints.

(5) Freedom from involuntary seclusion.

(d) *Standard: Confidentiality of patient records.* For any patient care records or election information it maintains on patients, the RNHCI must establish procedures to do the following:

(1) Safeguard the privacy of any information that identifies a particular patient. Information from, or copies of, records may be released only to authorized individuals, and the RNHCI must ensure that unauthorized individuals cannot gain access to or alter patient records. Original patient care records must be released only in accordance with Federal or State laws, court orders, or subpoenas.

(2) Maintain the records and information in an accurate and timely manner.

(3) Ensure timely access by patients to the records and other information that pertains to that patient.

(4) Abide by all Federal and State laws regarding confidentiality and disclosure for patient care records and election information.

§ 403.732 Condition of participation: Quality assessment and performance improvement.

The RNHCI must develop, implement, and maintain a quality assessment and performance improvement program.

(a) *Standard: Program scope.* (1) The quality assessment and performance improvement program must include, but is not limited to, measures to evaluate:

(i) Access to care.

(ii) Patient satisfaction.

(iii) Staff performance.

(iv) Complaints and grievances.

(v) Discharge planning activities.

(vi) Safety issues, including physical environment.

(2) In each of the areas listed in paragraph (a)(1) of this section, and any other areas the RNHCI includes, the RNHCI must do the following:

(i) Define quality assessment and performance improvement measures.

(ii) Describe and outline quality assessment and performance improvement activities appropriate for the services furnished by or in the RNHCI.

(iii) Measure, analyze, and track performance that reflect care and RNHCI processes.

(iv) Inform all patients, in writing, of the scope and responsibilities of the quality assessment and performance improvement program.

(3) The RNHCI must set priorities for performance improvement, considering the prevalence of and severity of identified problems.

(4) The RNHCI must act to make performance improvements and must track performance to assure that improvements are sustained.

(b) *Standard: Program responsibilities.* (1) The governing body, administration, and staff are responsible for ensuring that the quality assessment and performance improvement program addresses identified priorities in the RNHCI and are responsible for the development, implementation, maintenance, and performance improvement of assessment actions.

(2) The RNHCI must include all programs, departments, functions, and contracted services when developing, implementing, maintaining, and evaluating the program of quality assessment and performance improvement.

§ 403.734 Condition of participation: Food services.

The RNHCI must have an organized food service that is directed and adequately staffed by qualified personnel.

(a) *Standard: Sanitary conditions.* The RNHCI must furnish food to the patient that is obtained, stored, prepared, distributed, and served under sanitary conditions.

(b) *Standard: Meals.* The RNHCI must serve meals that furnish each patient with adequate nourishment in accordance with the recommended dietary allowances of the Food and Nutrition Board of the National Research Council, National Academy of Sciences. The RNHCI must do the following:

(1) Furnish food that is palatable, attractive, and at the proper temperature and consistency.

(2) Offer substitutes of similar nourishment to patients who refuse food served or desire alternative choices.

(3) Furnish meals at regular times comparable to normal mealtimes in the community. There must be no more than 14 hours between a substantial evening meal and breakfast the following day.

(4) The RNHCI must offer snacks at bedtime.

§ 403.736 Condition of participation: Discharge planning.

The RNHCI must have in effect a discharge planning process that applies to all patients. The process must assure that appropriate post-institution services are obtained for each patient, as necessary.

(a) *Standard: Discharge planning evaluation.* (1) The RNHCI must assess the need for a discharge plan for any patient identified as likely to suffer adverse consequences if there is no planning and for any other patient upon his or her request or at the request of his or her legal representative. This discharge planning evaluation must be initiated at admission and must include the following:

(i) An assessment of the possibility of a patient needing post-RNHCI services and of the availability of those services.

(ii) 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.

(2) The staff must complete the assessment on a timely basis so that arrangements for post-RNHCI care are made before discharge and so that unnecessary delays in discharge are avoided.

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

(b) *Standard: Discharge plan.* (1) 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.

(2) 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.

(3) The RNHCI must arrange for the initial implementation of the beneficiary's discharge plan.

(4) 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.

(5) The RNHCI must inform the beneficiary or legal representative about the beneficiary's post-RNHCI care requirements.

(6) 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.

(c) *Standard: Transfer or referral.* The RNHCI must transfer or refer patients in a timely manner to another facility (including a medical facility if requested by the beneficiary, or his or her legal representative) in accordance with § 403.730(b)(2).

(d) *Standard: Reassessment.* 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.

§ 403.738 Condition of participation: Administration.

An RNHCI must have written policies regarding its organization, services, and administration.

(a) *Standard: Compliance with Federal, State, and local laws.* The RNHCI must operate in compliance with all applicable Federal, State, and local laws, regulations, and codes including, but not limited to, those pertaining to the following:

(1) Protection against discrimination on the basis of race, color, national

origin, age, or handicap (45 CFR parts 80, 84, and 91).

(2) Protection of human research subjects (45 CFR part 46).

(3) Application of all safeguards to protect against the possibility of fraud and abuse (42 CFR part 455).

(b) *Standard: Governing body.* (1) The RNHCI must have a governing body, or a person designated to function as a governing body, that is legally responsible for establishing and implementing all policies regarding the RNHCI's management and operation.

(2) The governing body must appoint the administrator responsible for the management of the RNHCI.

(c) *Standard: Affiliations and disclosure.* (1) An affiliation is permissible if it is between one of the following:

(i) An individual serving as an uncompensated director, trustee, officer, or other member of the governing body of an RNHCI and a provider of medical treatment or services.

(ii) An individual who is a director, trustee, officer, employee, or staff member of an RNHCI and another individual, with whom he or she has a family relationship, who is affiliated with (or has an ownership interest in) a provider of medical treatment or services.

(iii) The RNHCI and an individual or entity furnishing goods or services as a vendor to both providers of medical treatment or services and RNHCIs.

(2) The RNHCI complies with the disclosure requirements of §§ 420.206 and 455.104 of this chapter.

(3) The RNHCI furnishes written notice, including the identity of each new individual or company, to HCFA at the time of a change, if a change occurs in any of the following:

(i) Persons with an ownership or control interest, as defined in §§ 420.201 and 455.101 of this chapter.

(ii) The officers, directors, agents, or managing employees.

(iii) The religious entity, corporation, association, or other company responsible for the management of the RNHCI.

(iv) The RNHCI's administrator or director of nonmedical nursing services.

§ 403.740 Condition of participation: Staffing.

The RNHCI must be staffed with qualified experienced personnel who are present in sufficient numbers to meet the needs of the patients.

(a) *Standard: Personnel qualifications.* The RNHCI must ensure that staff who supervise or furnish services to patients are qualified to do so and that staff allowed to practice without direct supervision have specific training to furnish these services.

(b) *Standard: Education, training, and performance evaluation.* (1) The RNHCI must ensure that staff (including contractors and other individuals working under arrangement) have the necessary education and training concerning their duties so that they can furnish services competently. This education includes, but is not limited to, training related to the individual job description, performance expectations, applicable organizational policies and procedures, and safety responsibilities.

(2) Staff must demonstrate, in practice, the skills and techniques necessary to perform their duties and responsibilities.

(3) The RNHCI must evaluate the performance of staff and implement measures for improvement.

§ 403.742 Condition of participation: Physical environment.

A RNHCI must be designed, constructed, and maintained to ensure the safety of the patients, staff, and the public.

(a) *Standard: Buildings.* The physical plant and the overall environment must be maintained in a manner that ensures the safety and well-being of the patients. The RNHCI must have the following:

(1) Emergency power for emergency lights, for fire detection and alarm systems, and for fire extinguishing systems.

(2) Procedures for the proper storage and disposal of trash.

(3) Proper ventilation and temperature control and appropriate lighting levels to ensure a safe and secure environment.

(4) A written disaster plan to address loss of power, water, sewage, and other emergencies.

(5) Facilities for emergency gas and water supply.

(6) An effective pest control program.

(7) A preventive maintenance program to maintain essential mechanical, electrical, and fire protection equipment operating in an efficient and safe manner.

(8) A working call system for patients to summon aid or assistance.

(b) *Standard: Patient rooms.* Patient rooms must be designed and equipped for adequate care, comfort, and privacy of the patient.

(1) Patient rooms must meet the following conditions:

(i) Accommodate no more than four patients.

(ii) Measure at least 80 square feet per patient in multiple patient rooms and at least 100 square feet in single patient rooms.

(iii) Have direct access to an exit corridor.

(iv) Be designed or equipped to assure full visual privacy for each patient.

(v) Have at least one window to the outside.

(vi) Have a floor at or above grade level.

(2) The RNHCI must furnish each patient with the following:

(i) A separate bed of proper size and height for the convenience of the patient.

(ii) A clean, comfortable mattress.

(iii) Bedding appropriate to the weather and climate.

(iv) Functional furniture appropriate to the patient's needs and individual closet space with clothes racks and shelves accessible to the patient.

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

(i) Are in accordance with the special needs of the patients.

(ii) Will not adversely affect patients' health and safety.

§ 403.744 Condition of participation: Life safety from fire.

(a) *General.* An RNHCI must meet the following conditions:

(1) Except as provided in paragraph (b) of this section, the RNHCI must meet the new or existing health care occupancies provisions of the 1997 edition of the Life Safety Code of the National Fire Protection Association (NFPA 101), which is incorporated by reference. Incorporation by reference of NFPA 101, the Life Safety Code, 1997 edition, was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.[1] (See § 483.70).

(2) The RNHCI must have written fire control plans that contain provisions for prompt reporting of fires; extinguishing fires; protection of patients, staff, and the public; evacuation; and cooperation with fire fighting authorities.

(3) The RNHCI must maintain written evidence of regular inspection and approval by State or local fire control agencies.

(b) *Exceptions.* (1) If application of the Life Safety Code required under

[1] The 1997 edition of the Life Safety Code (NFPA 101) is available for inspection at the HCFA Information Resource Center, 7500 Security Boulevard, Central Building, Baltimore, MD, and at the Office of the Federal Register, 800 North Capitol Street, NW, suite 700, Washington, DC. Copies of this publication may be purchased from the National Fire Protection Association, 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02263–9101.

paragraph (a)(1) of this section would result in unreasonable hardship upon the RNHCI, HCFA may waive specific provisions of the Life Safety Code, but only if the waiver does not adversely affect the health and safety of patients.

(2) If HCFA finds that the fire and safety code imposed by State law adequately protects patients in the institution, the provisions of the Life Safety Code required in paragraph (a)(1) of this section do not apply in that State.

§ 403.746 Condition of participation: Utilization review.

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.

(a) *Standard: Utilization review plan.* The utilization review plan must contain written procedures for evaluating the following:

(1) Admissions.

(2) Duration of care.

(3) Continuing care of an extended duration.

(4) Items and services furnished.

(b) *Standard: Utilization review committee.* The committee is responsible for evaluating each admission and ensuring that the admission is necessary and appropriate. The utilization review plan must be carried out by the utilization review committee, consisting of the governing body, administrator or other individual responsible for the overall administration of the RNHCI, the supervisor of nursing staff, and other staff as appropriate.

§ 403.750 Estimate of expenditures and adjustments.

(a) *Estimates.* HCFA estimates the level of expenditures for services provided under this subpart before the start of each FFY beginning with FFY 2000.

(b) *Adjustments to payments.* When the level of estimated expenditures is projected to exceed the FFY trigger level as described in paragraph (d) of this section, for the year of the projection, payments to RNHCIs will be reduced by a proportional percentage to prevent estimated expenditures from exceeding the trigger level. In addition to reducing payments proportionally, HCFA may impose alternative adjustments.

(c) *Notification of adjustments.* HCFA notifies participating RNHCIs before the start of the FFY of the type and level of expenditure reductions to be made and when these adjustments will apply.

(d) *Calculation of trigger level.* The trigger level for FFY 1998 is $20,000,000. For subsequent FFYs, the trigger level is the unadjusted trigger level increased or decreased by the carry forward as described in § 403.754(b). The unadjusted trigger level is the base year amount (the unadjusted trigger level dollar amount for the prior FFY) increased by the average consumer price index (the single numerical value published monthly by the Bureau of Labor Statistics that presents the relationship in United States urban areas for the current cost of goods and services compared to a base year, to represent the change in spending power) for the 12-month period ending on July 31 preceding the beginning of the FFY.

§ 403.752 Payment provisions.

(a) *Payment to RNHCIs.* Payment for services may be made to an RNHCI that meets the conditions for coverage described in § 403.720 and the conditions of participation described in §§ 403.730 through 403.746. Payment is made in accordance with § 413.40 of this chapter to an RNHCI meeting these conditions.

(b) *Review of estimates and adjustments.* There is no administrative or judicial review of the level of estimated expenditures or the adjustments in payments described in §§ 403.750(a) and (b).

(c) *Effect on beneficiary liability.* When payments are reduced in accordance with § 403.750(b), the RNHCI may bill the beneficiary the amount of the Medicare reduction attributable to his or her covered services.

(d) *Notification of beneficiary liability.* (1) 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 at least 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.

(2) 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).

§ 403.754 Monitoring expenditure level.

(a) *Tracking expenditures.* Starting in FFY 1999 HCFA begins monitoring Medicare payments to RNHCIs.

(b) *Carry forward.* The difference between the trigger level and Medicare expenditures for a FFY results in a carry forward that either increases or decreases the unadjusted trigger level described in § 403.750(d). In no case may the carry forward exceed $50,000,000 for an FFY.

§ 403.756 Sunset provision.

(a) *Effective date.* Beginning with FFY 2002, if the level of estimated expenditures for all RNHCIs exceeds the trigger level for 3 consecutive FFYs, HCFA will not accept as the basis for payment of any claim any election executed on or after January 1 of the following calendar year.

(b) *Notice of activation.* A notice in the **Federal Register** will be published at least 60 days before January 1 of the calendar year that the sunset provision becomes effective.

(c) *Effects of sunset provision.* Only those beneficiaries who have a valid election in effect before January 1 of the year in which the sunset provision becomes effective will be able to claim Medicare payment for care in an RNHCI, and only for RNCHI services furnished during that election.

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SYSTEMS

1. The authority citation for part 412 continues to read as follows:

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

§ 412.90 [Removed]

2. In § 412.90, paragraph (c) is removed and reserved.

§ 412.98 [Removed]

3. Section 412.98 is removed and reserved.

PART 440—SERVICES: GENERAL PROVISIONS

1. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

2. In § 440.170, paragraphs (b) and (c) are revised to read as follows:

§ 440.170 Any other medical care or remedial care recognized under State law and specified by the Secretary.

* * * * *

(b) *Services furnished in a religious nonmedical health care institution.* Services furnished in a religious nonmedical health care institution are services furnished in an institution that:

(1) Is an institution that is described in (c)(3) of section 501 of the Internal Revenue Code of 1986 and is exempt from taxes under section 501(a) of that section.

(2) Is lawfully operated under all applicable Federal, State, and local laws and regulations.

(3) Furnishes only nonmedical nursing items and services to patients who choose to rely solely upon a religious method of healing and for whom the acceptance of medical health services would be inconsistent with their religious beliefs.

(4) Furnishes nonmedical items and services exclusively through nonmedical nursing personnel who are experienced in caring for the physical needs of nonmedical patients.

(5) Furnishes these nonmedical items and services to inpatients on a 24-hour basis.

(6) Does not furnish, on the basis of its religious beliefs, through its personnel or otherwise, medical items and services (including any medical screening, examination, diagnosis, prognosis, treatment, or the administration of drugs) for its patients.

(7) Is not owned by, is not under common ownership with, or does not have an ownership interest of 5 percent or more in, a provider of medical treatment or services and is not affiliated with a provider of medical treatment or services or with an individual who has an ownership interest or 5 percent or more in a provider of medical treatment or services. Permissible affiliations are described in paragraph (c) of this section.

(8) Has in effect a utilization review plan that meets the following criteria:

(i) Provides for the review of admissions to the institution, duration of stays, cases of continuous extended duration, and items and services furnished by the institution.

(ii) Requires that the reviews be made by a committee of the institution that included the individuals responsible for overall administration and for supervision of nursing personnel at the institution.

(iii) Provides that records be maintained of the meetings, decisions, and actions of the utilization review committee.

(iv) Meets other requirements as HCFA finds necessary to establish an effective utilization review plan.

(9) Provides information HCFA may require to implement section 1821 of the Act, including information relating to quality of care and coverage determinations.

(10) Meets other requirements as HCFA finds necessary in the interest of the health and safety of patients who receive services in the institution. These requirements are the conditions of participation found at part 403, subpart G of this chapter.

(c) *Affiliations.* An affiliation is permissible for purposes of paragraph (b)(7) of this section if it is between one of the following:

(1) An individual serving as an uncompensated director, trustee, officer, or other member of the governing body of an RNHCI and a provider of medical treatment or services.

(2) An individual who is a director, trustee, officer, employee, or staff member of an RNHCI and an another individual, with whom he or she has a family relationship, who is affiliated with (or has an ownership interest in) a provider of medical treatment or services.

(3) The RNHCI and an individual or entity furnishing goods or services as a vendor to both providers of medical treatment or services and RNHCIs.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND, ENFORCEMENT PROCEDURES

1. The authority citation for part 488 continues to read as follows:

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

2. Section 488.2 is amended by adding ''1861(ss)(2)—Accreditation of religious nonmedical health care institutions.'' after ''1861(ee)—Discharge planning guidelines for hospitals'' and before ''1864—Use of State survey agencies.''

3. Section 488.6 (a) is amended by adding ''religious nonmedical health care institutions;'' after ''hospices;'' and before ''screening mammography services;''

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

1. The authority citation for part 489 is revised to read as follows:

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

2. In § 489.102, introductory paragraph (a) is republished and paragraph (a)(2) 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:

* * * * *

(2) Document in a prominent part of the individual's current medical record, or patient care record in the case of an individual in a religious nonmedical health care institution, whether or not the individual has executed an advance directive;

* * * * *

PARTS 431, 440, 442, 456 and 466—[AMENDED]

1. In the following sections, ''Christian Science Sanitoria operated or listed and certified, by the First Church of Christ Scientist, Boston, Mass.'' is revised to read ''religious nonmedical institutions as defined in § 440.170(b) of this chapter'':

a. § 431.610(b);

b. § 442.12(b); and

c. § 456.601.

2. In the following sections, ''a Christian Science Sanitorium, operated or listed and certified, by the First Church of Christ Scientist, Boston, Mass.'' is revised to read ''a religious nonmedical institution as defined in § 440.170(b) of this chapter'':

a. § 431.701(a); and

b. § 466.1

3. In § 440.155(b)(1), ''Christian Science sanatorium operated, or listed and certified by the First Church of Christ, Scientist, Boston Mass.'' is revised to read ''religious nonmedical institution as defined in § 440.170(b).''

4. In § 456.351, ''Christian Science Sanitoria'' is revised to read ''religious nonmedical institutions as defined in § 440.170(b) of this chapter''.

(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: November 17, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: April 29, 1999.

Donna E. Shalala,

Secretary.

Note: This document was received at the Office of the Federal Register on November 15, 1999.

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