

(2) The amount imposed is not less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including but not limited to the costs attributable to the investigation, prosecution, and administrative review of the case.

(3) Nothing in this section limits the authority of CMS or OIG to settle any issue or case as provided by §402.19 or to compromise any penalty and assessment as provided by §402.115.

**§402.113 When a penalty and assessment are collectible.**

A civil money penalty and assessment become collectible after the earliest of the following:

(a) Sixty days after the respondent receives CMS's or OIG's notice of proposed determination under §402.7, if the respondent has not requested a hearing before an ALJ.

(b) Immediately after the respondent abandons or waives his or her appeal right at any administrative level.

(c) Thirty days after the respondent receives the ALJ's decision imposing a civil money penalty or assessment under §1005.20(d) of this title, if the respondent has not requested a review before the DAB.

(d) If the DAB grants an extension of the period for requesting the DAB's review, the day after the extension expires if the respondent has not requested the review.

(e) Immediately after the ALJ's decision denying a request for a stay of the effective date under §1005.22(b) of this title.

(f) If the ALJ grants a stay under §1005.22(b) of this title, immediately after the judicial ruling is completed.

(g) Sixty days after the respondent receives the DAB's decision imposing a civil money penalty if the respondent has not requested a stay of the decision under §1005.22(b) of this title.

**§402.115 Collection of penalty or assessment.**

(a) Once a determination by HHS has become final, CMS is responsible for the collection of any penalty or assessment.

(b) The General Counsel may compromise a penalty or assessment im-

posed under this part, after consultation with CMS or OIG, and the Federal government may recover the penalty or assessment in a civil action brought in the United States district court for the district where the claim was presented or where the respondent resides.

(c) The United States or a State agency may deduct the amount of a penalty and assessment when finally determined, or the amount agreed upon in compromise, from any sum then or later owing to the respondent.

(d) Matters that were raised or that could have been raised in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

**Subpart C—Exclusions [Reserved]**

**PART 403—SPECIAL PROGRAMS AND PROJECTS**

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## § 403.200

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AUTHORITY: 42 U.S.C. 1359b-3 and secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

### Subpart A [Reserved]

### Subpart B—Medicare Supplemental Policies

SOURCE: 47 FR 32400, July 26, 1982, unless otherwise noted.

## § 403.200 Basis and scope.

(a) *Provisions of the legislation.* This subpart implements, in part, section 1882 of the Social Security Act. The intent of that section is to enable Medicare beneficiaries to identify Medicare supplemental policies that do not duplicate Medicare, and that provide adequate, fairly priced protection against expenses not covered by Medicare. The legislation establishes certain standards for Medicare supplemental policies and provides two methods for informing Medicare beneficiaries which policies meet those standards:

(1) Through a State approved program, that is, a program that a Supplemental Health Insurance Panel determines to meet certain minimum requirements for the regulation of Medicare supplemental policies; and

(2) In a State without an approved program, through certification by the Secretary of policies voluntarily submitted by insuring organizations for review against the standards.

(b) *Scope of subpart.* This subpart sets forth the standards and procedures CMS will use to implement the voluntary certification program.

#### GENERAL PROVISIONS

##### § 403.201 State regulation of insurance policies.

(a) The provisions of this subpart do not affect the right of a State to regulate policies marketed in that State.

(b) Approval of a policy under the voluntary certification program, as provided for in § 403.235(b), does not authorize the insuring organization to market a policy that does not conform to applicable State laws and regulations.

##### § 403.205 Medicare supplemental policy.

(a) Except as specified in paragraph (d) of this section, *Medicare supplemental policy* (policy) means a health insurance policy or other health benefit plan—

(1) That a private entity offers to a Medicare beneficiary; and

(2) That is primarily designed, or is advertised, marketed, or otherwise purported to provide payment for expenses incurred for services and items that are not reimbursed under the Medicare program because of deductibles, coinsurance, or other limitations under Medicare.

(b) Unless otherwise specified in this subpart, the term *policy* includes both policy form and policy.

(1) *Policy form* means the form of health insurance contract that is approved by and on file with the State agency for the regulation of insurance.

(2) *Policy* means the contract—

(i) Issued under the policy form; and

(ii) Held by the policyholder.

(c) Medicare supplemental policy includes the following—

(1) An individual policy.

(2) A group policy.

(d) Medicare supplemental policy does not include a Medicare+Choice plan or any of the following health insurance policies or health benefit plans:

(1) A policy or plan of one or more employers for employees, former employees, or any combination thereof.

(2) A policy or plan of one or more labor organizations for members, former members, or any combination thereof.

(3) A policy or plan of the trustees of a fund established by one or more labor organizations, one or more employers, or any combination, for any one or combination of the following—

(i) Employees.

(ii) Former employees.

(iii) Members.

(iv) Former members.

(4) A policy or plan of a profession, trade, or occupational association, if the association—

(i) Is composed of individuals all of whom are actively engaged in the same profession, trade, or occupation;

(ii) Has been maintained in good faith for a purpose other than obtaining insurance; and

(iii) Has been in existence for at least two years before the date of its initial offering of a Medicare supplemental health insurance policy to its members.

(5) For purposes of the voluntary certification program, a policy issued to an employee or to a member of a labor organization as an addition to a franchise plan (a plan that enables members of the same entity to purchase an individual policy marketed to them under group underwriting procedures), if the plan is in existence on July 1, 1982.

[47 FR 32400, July 26, 1982, as amended at 63 FR 35066, June 26, 1998]

##### § 403.206 General standards for Medicare supplemental policies.

(a) For purposes of the voluntary certification program described in this subpart, a policy must meet—

(1) The National Association of Insurance Commissioners (NAIC) model standards as defined in § 405.210; and

## § 403.210

(2) The loss ratio standards specified in § 403.215.

(b) Except as specified in paragraph (c) of this section, the standards specified in paragraph (a) of this section must be met in a single policy.

(c) In the case of a nonprofit hospital or a medical association where State law prohibits the inclusion of all benefits in a single policy, the standards specified in paragraph (a) of the section must be met in two or more policies issued in conjunction with one another.

### § 403.210 NAIC model standards.

(a) *NAIC model standards* means the National Association of Insurance Commissioners (NAIC) "Model Regulation to Implement the Individual Accident and Insurance Minimum Standards Act" (as amended and adopted by the NAIC on June 6, 1979, as it applies to Medicare supplemental policies). Copies of the NAIC model standards can be purchased from the National Association of Insurance Commissioners at 350 Bishops Way, Brookfield, Wisconsin 53004, and from the NIARS Corporation, 318 Franklin Avenue, Minneapolis, Minnesota 55404.

(b) The policy must comply with the provisions of the NAIC model standards, except as follows—

(1) *Policy*, for purposes of this paragraph, means individual and group policy, as specified in § 403.205. The NAIC model standards limit "policy" to individual policy.

(2) The policy must meet the loss ratio standards specified in § 403.215.

[47 FR 32400, July 26, 1982; 49 FR 44472, Nov. 7, 1984]

### § 403.215 Loss ratio standards.

(a) The policy must be expected to return to the policyholders, in the form of aggregate benefits provided under the policy—

(1) At least 75 percent of the aggregate amount of premiums in the case of group policies; and

(2) At least 60 percent of the aggregate amount of premiums in the case of individual policies.

(b) For purposes of loss ratio requirements, policies issued as a result of solicitation of individuals through the mail or by mass media advertising are considered individual policies.

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### STATE REGULATORY PROGRAMS

#### § 403.220 Supplemental Health Insurance Panel.

(a) *Membership*. The Supplemental Health Insurance Panel (Panel) consists of—

(1) The Secretary or a designee, who serves as chairperson, and

(2) Four State Commissioners or Superintendents of Insurance appointed by the President. (The terms Commissioner or Superintendent of Insurance include persons of similar rank.)

(b) *Functions*. (1) The Panel determines whether or not a State regulatory program for Medicare supplemental health insurance policies meets and continues to meet minimum requirements specified in section 1882 of the Social Security Act.

(2) The chairperson of the Panel informs the State Commissioners and Superintendents of Insurance of all determinations made under paragraph (b)(1) of this section.

#### § 403.222 State with an approved regulatory program.

(a) A State has an approved regulatory program if the Panel determines that the State has in effect under State law a regulatory program that provides for the application of standards, with respect to each Medicare supplemental policy issued in that State, that are equal to or more stringent than those specified in section 1882 of the Social Security Act.

(b) *Policy issued in that State* means—

(1) A group policy, if the holder of the master policy resides in that State; and

(2) An individual policy, if the policy is—

(i) Issued in that State; or

(ii) Issued for delivery in that State.

(c) A policy issued in a State with an approved regulatory program is considered to meet the NAIC model standards in § 403.210 and loss ratio standards in § 403.215.

### VOLUNTARY CERTIFICATION PROGRAM: GENERAL PROVISIONS

#### § 403.231 Emblem.

(a) The emblem is a graphic symbol, approved by HHS, that indicates that

CMS has certified a policy as meeting the requirements of the voluntary certification program, specified in § 403.232.

(b) Unless prohibited by the State in which the policy is marketed, the insuring organization may display the emblem on policies certified under the voluntary certification program.

(c) The manner in which the emblem may be displayed and the conditions and restrictions relating to its use will be stated in the letter with which CMS notifies the insuring organization that a policy has been certified. The insuring organization must comply with these conditions and restrictions.

(d) If a certified policy is issued in a State that later has an approved regulatory program, as provided for in § 403.222, the insuring organization may display the emblem on the policy until the earliest of the following—

(1) When prohibited by State law or regulation.

(2) When the policy no longer meets the requirements for Medicare supplemental policies specified in § 403.206.

(3) The date the insuring organization would be required to submit material to CMS for annual review in order to retain certification, if the State did not have an approved program (see § 403.239).

**§ 403.232 Requirements and procedures for obtaining certification.**

(a) To be certified by CMS, a policy must meet—

(1) The NAIC model standards specified in § 403.210;

(2) The loss ratio standards specified in § 403.215; and

(3) Any State requirements applicable to a policy—

- (i) Issued in that State; or
- (ii) Marketed in that State.

(b) An insuring organization requesting certification of a policy must submit the following to CMS for review—

(1) A copy of the policy form (including all the documents that would constitute the contract of insurance that is proposed to be marketed as a certified policy).

(2) A copy of the application form including all attachments.

(3) A copy of the uniform certificate issued under a group policy.

(4) A copy of the outline of coverage, in the form prescribed by the NAIC model standards.

(5) A copy of the Medicare supplement buyers' guide to be provided to all applicants if the buyers' guide is not the CMS/NAIC buyers' guide.

(6) A statement of when and how the outline of coverage and the buyers' guide will be delivered and copies of applicable receipt forms.

(7) A copy of the notice of replacement and statement as to when and how that notice will be delivered.

(8) A list of States in which the policy is authorized for sale. If the policy was approved under a deemer provision in any State, the conditions involved must be specified.

(9) A copy of the loss ratio calculations, as specified in § 403.250.

(10) Loss ratio supporting data, as specified in § 403.256.

(11) A statement of actuarial opinion, as specified in § 403.258.

(12) A statement that the insuring organization will notify the policyholders in writing, within the period of time specified in § 403.245(c), if the policy is identified as a certified policy at the time of sale and later loses certification.

(13) A signed statement in which the president of the insuring organization, or a designee, attests that—

(i) The policy meets the requirements specified in paragraph (a) of this section; and

(ii) The information submitted to CMS for review is accurate and complete and does not misrepresent any material fact.

**§ 403.235 Review and certification of policies.**

(a) CMS will review policies that the insuring organization voluntarily submits, except that CMS will not review a policy issued in a State with an approved regulatory program under § 403.222.

(b) If the requirements specified in § 403.232 are met, CMS will—

- (1) Certify the policy; and
- (2) Authorize the insuring organization to display the emblem on the policy, as provided for in § 403.231.

(c) If CMS certifies a policy, it will inform all State Commissioners and

**§ 403.239**

Superintendents of Insurance of that fact.

**§ 403.239 Submittal of material to retain certification.**

(a) CMS certification of a policy that continues to meet the standards will remain in effect, if the insuring organization files the following material with CMS no later than the date specified in paragraph (b) or (c) of this section—

(1) Any changes in the material, specified in § 403.232(b), that was submitted for previous certification.

(2) The loss ratio supporting data specified in § 403.256(b).

(3) A signed statement in which the president of the insuring organization, or a designee, attests that—

(i) The policy continues to meet the requirements specified in § 403.232(a); and

(ii) The information submitted to CMS for review is accurate and complete and does not misrepresent any material fact.

(b) Except as specified in paragraph (c) of this section, the insuring organization must file the material with CMS no later than June 30 of each year. The first time the insuring organization must file the material is no later than June 30 of the calendar year that follows the year in which CMS—

(1) Certifies a new policy; or

(2) Certifies a policy that lost certification as provided in § 403.245.

(c) If the loss ratio calculation period, used to calculate the expected loss ratio for the last actuarial certification submitted to CMS, ends before the June 30 date of paragraph (b) of this section, the insuring organization must file the material with CMS no later than the last day of that rate calculation period.

**§ 403.245 Loss of certification.**

(a) A policy loses certification if—

(1) The insuring organization withdraws the policy from the voluntary certification program; or

(2) CMS determines that—

(i) The policy fails to meet the requirements specified in § 403.232(a); or

(ii) The insuring organization has failed to meet the requirements for submittal of material specified in § 403.239.

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(b) If a policy loses its certification, CMS will inform all State Commissioners and Superintendents of Insurance of that fact.

(c) If a policy that displays the emblem, or that has been marketed as a certified policy without the emblem, loses certification, the insuring organization must notify each holder of the policy, or of a certificate issued under the policy, of that fact. The notice must be in writing and sent by the earlier of—

(1) The date of the first regular premium notice after the date the policy loses its certification; or

(2) 60 days after the date the policy loses its certification.

**§ 403.248 Administrative review of CMS determinations.**

(a) This section provides for administrative review if CMS determines—

(1) Not to certify a policy; or

(2) That a policy no longer meets the standards for certification.

(b) If CMS makes a determination specified in paragraph (a) of this section, it will send a notice to the insuring organization containing the following information:

(1) That CMS has made such a determination.

(2) The reasons for the determination.

(3) That the insuring organization has 30 days from the date of the notice to—

(i) Request, in writing, an administrative review of the CMS determination; and

(ii) Submit additional information to CMS for review.

(4) That, if the insuring organization requests an administrative review, CMS will conduct the review, as provided for in paragraph (c) of this section.

(5) That, in a case involving loss of certification, the CMS determination will go into effect 30 days from the date of the notice, unless the insuring organization requests an administrative review. If the insuring organization requests an administrative review, the policy retains its certification until CMS makes a final determination.

(c) If the insuring organization requests an administrative review, CMS will conduct the review as follows—

(1) A CMS official, not involved in the initial CMS determination, will initiate and complete an administrative review within 90 days of the date of the notice provided for in paragraph (b) of this section.

(2) The official will consider—

(i) The original material submitted to CMS for review, as specified in § 403.232(b) or § 403.239(a); and

(ii) Any additional information, that the insuring organization submits to CMS.

(3) Within 15 days after the administrative review is completed, CMS will inform the insuring organization in writing of the final decision, with an explanation of the final decision.

(4) If the final decision is that a policy lose its certification, the loss of certification will go into effect 15 days after the date of CMS's notice informing the insuring organization of the final decision.

VOLUNTARY CERTIFICATION PROGRAM:  
LOSS RATIO PROVISIONS

**§ 403.250 Loss ratio calculations: General provisions.**

(a) *Basic formula.* The expected loss ratio is calculated by determining the ratio of benefits to premiums.

(b) *Calculations.* The insuring organization must calculate loss ratios according to the provisions of §§ 403.251, 403.253, and 403.254.

**§ 403.251 Loss ratio date and time frame provisions.**

(a) *Initial calculation date* means the first date of the period that the insuring organization uses to calculate the policy's expected loss ratio.

(1) The initial calculation date may be before, the same as, or after the date the insuring organization sends the policy to CMS for review, except—

(2) The initial calculation date must not be earlier than January 1 of the calendar year in which the policy is sent to CMS.

(b) *Loss ratio calculation period* means the period beginning with the initial calculation date and ending with the last day of the period for which the in-

surging organization calculates the policy's scale of premiums.

(c) To calculate "present values", the insuring organization may ignore discounting (an actuarial procedure that provides for the impact of a variety of factors, such as lapse of policies) for loss ratio calculation periods not exceeding 12 months.

**§ 403.253 Calculation of benefits.**

(a) *General provisions.* (1) Except as provided for in paragraph (a)(2) of this section, calculate the amount of "benefits" by—

(i) Adding the present values on the initial calculation date of—

(A) Expected incurred benefits in the loss ratio calculation period, to—

(B) The total policy reserve at the last day of the loss ratio calculation period; and

(ii) Subtracting the total policy reserve on the initial calculation date from the sum of these values.

(2) To calculate the amount of "benefits" in the case of community or pool rated individual or group policies rerated on an annual basis, calculate the expected incurred benefits in the loss ratio calculation period.

(b) *Calculation of total policy reserve—*

(1) *Option for calculation.* The insuring organization must calculate "total policy reserve" according to the provisions of paragraph (b) (2) or (3) of this section.

(2) *Total policy reserve: Federal provisions.* (i) "Total policy reserve" means the sum of—

(A) Additional reserve; and

(B) The reserve for future contingent benefits.

(ii) *Additional reserve* means the amount calculated on a net level reserve basis, using appropriate values to account for lapse, mortality, morbidity, and interest, that on the valuation date represents—

(A) The present value of expected incurred benefits over the loss ratio calculation period; less—

(B) The present value of expected net premiums over the loss ratio calculation period.

(iii) *Net premium* means the level portion of the gross premium used in calculating the additional reserve. On the day the policy is issued, the present

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value of the series of those portions equals the present value of the expected incurred claims over the period that the gross premiums are computed to provide coverage.

(iv) *Reserve for future contingent benefits* means the amounts, not elsewhere included, that provide for the extension of benefits after insurance coverage terminates. These benefits—

(A) Are predicated on a health condition existing on the date coverage ends;

(B) Accrue after the date coverage ends; and

(C) Are payable after the valuation date.

(3) *Total policy reserve: State provisions*. “Total policy reserve” means the total policy reserve calculated according to appropriate State law or regulation.

**§ 403.254 Calculation of premiums.**

(a) *General provisions*. To calculate the amount of “premiums”, calculate the present value on the initial calculation date of expected earned premiums for the loss ratio calculation period.

(b) *Specific provisions*. (1) *Earned premium* for a given period means—

(i) Written premiums for the period; plus—

(ii) The total premium reserve at the beginning of the period; less—

(iii) The total premium reserve at the end of the period.

(2) *Written premiums in a period* means—

(i) Premiums collected in that period; plus—

(ii) Premiums due and uncollected at the end of that period; less—

(iii) Premiums due and uncollected at the beginning of that period.

(3) *Total premium reserve* means the sum of—

(i) The unearned premium reserve;

(ii) The advance premium reserve; and

(iii) The reserve for rate credits.

(4) *Unearned premium reserve* means the portion of gross premiums due that provide for days of insurance coverage after the valuation date.

(5) *Advance premium reserve* means premiums received by the insuring or-

ganization that are due after the valuation date.

(6) *Reserve for rate credits* means rate credits on a group policy that—

(i) Accrue by the valuation date of the policy; and

(ii) Are paid or credited after the valuation date.

**§ 403.256 Loss ratio supporting data.**

(a) For purposes of requesting CMS certification under § 403.232, the insuring organization must submit the following loss ratio data to CMS for review—

(1) A statement of why the policy is to be considered, for purposes of the loss ratio standards, an individual or a group policy.

(2) The earliest age at which policyholders can purchase the policy.

(3) The general marketing method and the underwriting criteria used for the selection of applicants to whom coverage is offered.

(4) What policies are to be included under the one policy form, by the dates the policies are issued.

(5) The loss ratio calculation period.

(6) The scale of premiums for the loss ratio calculation period.

(7) The expected level of earned premiums in the loss ratio calculation period.

(8) The expected level of incurred claims in the loss ratio calculation period.

(9) A description of how the following assumptions were used in calculating the loss ratio.

(i) Morbidity.

(ii) Mortality.

(iii) Lapse.

(iv) Assumed increases in the Medicare deductible.

(v) Impact of inflation on reimbursement per service.

(vi) Interest.

(vii) Expected distribution, by age and sex, of persons who will purchase the policy in the coming year.

(viii) Expected impact on morbidity by policy duration of—

(A) The process used to select insureds from among those that apply for a policy; and

(B) Pre-existing condition clauses in the policy.

(b) For purposes of requesting continued CMS certification under § 403.239(a), the insuring organization must submit the following to CMS—

(1) A description of all changes in the loss ratio data, specified in paragraph (a) of this section, that occurred since CMS last reviewed the policy.

(2) The past loss ratio experience for the policy, including the experience of all riders and endorsements issued under the policy. The loss ratio experience data must include earned premiums, incurred claims, and total policy reserves that the insuring organization calculates—

(i) For all years of issue combined; and

(ii) Separately for each calendar year since CMS first certified the policy.

**§ 403.258 Statement of actuarial opinion.**

(a) For purposes of certification requests submitted under § 403.232(b) and subsequent review as specified in § 403.239(a), *statement of actuarial opinion* means a signed declaration in which a qualified actuary states that the assumptions used in calculating the expected loss ratio are appropriate and reasonable, taking into account actual policy experience, if any, and reasonable expectations.

(b) *Qualified actuary* means—

(1) A member in good standing of the American Academy of Actuaries; or

(2) A person who has otherwise demonstrated his or her actuarial competence to the satisfaction of the Commissioner or Superintendent of Insurance of the domiciliary State of the insuring organization.

**Subpart C—Recognition of State Reimbursement Control Systems**

SOURCE: 51 FR 15492, Apr. 24, 1986, unless otherwise noted.

**§ 403.300 Basis and purpose.**

(a) *Basis*. This subpart implements section 1886(c) of the Act, which authorizes payment for Medicare inpatient hospital services in accordance with a State's reimbursement control system rather than under the Medicare reimbursement principles as described in CMS's regulations and instructions.

(b) *Purpose*. Contained in this subpart are—

(1) The basic requirements that a State reimbursement control system must meet in order to be approved by CMS;

(2) A description of CMS's review and evaluation procedures; and

(3) The conditions that apply if the system is approved.

**§ 403.302 Definitions.**

For purposes of this subpart—

*Chief executive officer of a State* means the Governor of the State or the Governor's designee.

*Existing demonstration project* refers to demonstration projects approved by CMS under the authority of section 402(a) of the Social Security Amendments of 1967 (42 U.S.C. 1395b-1) or section 222(a) of the Social Security Amendments of 1972 (42 U.S.C. 1395b-1 (note)) and in effect on April 20, 1983 (the date of the enactment of Pub. L. 98-21 (Social Security Amendments of 1983)).

*Federal hospital* means a hospital that is administered by, or that is under exclusive contract with, the Department of Defense, the Veterans Administration, or the Indian Health Service.

*State system* or *system* refers to a State reimbursement control system that is approved by CMS under the authority of section 1886(c) of the Act and that satisfies the requirements described in this subpart.

**§ 403.304 Minimum requirements for State systems—discretionary approval.**

(a) *Discretionary approval by CMS*. CMS may approve Medicare payments under a State system, if CMS determines that the system meets the requirements in paragraphs (b) and (c) of this section and, if applicable paragraph (d) of this section.

(b) *Requirements for State system*. (1) An application for approval of the system must be submitted to CMS by the Chief Executive Officer of the State.

(2) The State system must apply to substantially all non-Federal acute care hospitals in the State.

(3) All hospitals covered by the system must have and maintain a utilization and quality control review agreement with a Quality Improvement Organization, as required under section 1866(a)(1)(F) of the Act and § 466.78(a) of this chapter.

(4) Federal hospitals must be excluded from the State system.

(5) Nonacute care or specialty hospital (such as rehabilitation, psychiatric, or children's hospitals) may, at the option of the State, be excluded from the State system.

(6) The State system must apply to at least 75 percent of all revenues or expenses—

(i) For inpatient hospital services in the State; and

(ii) For inpatient hospital services under the State's Medicaid plan.

(7) Under the system, HMOs and competitive medical plans (CMPs), as defined by section 1876(b) of the Act and part 417 of this chapter, must be allowed to negotiate payment rates with hospitals.

(8) The system must limit hospital charges for Medicare beneficiaries to deductibles, coinsurance or non-covered services.

(9) Unless a waiver is granted by CMS under § 489.23 of this chapter, the system must prohibit payment, as required under section 1862(a)(14) of the Act and § 405.310(m) of this chapter, for nonphysician services provided to hospital inpatients under Part B of Medicare.

(10) The system must require hospitals to submit Medicare cost reports or approved reports in lieu of Medicare cost reports as required.

(11) The system must require—

(i) Preparation, collection, or retention by the State of reports (such as financial, administrative, or statistical reports) that may be necessary, as determined by CMS, to review and monitor the State's assurances; and

(ii) Submission of the reports to CMS upon request.

(12) The system must provide hospitals an opportunity to appeal errors that they believe have been made in the determination of their payment rates. The system, if it is prospective may not permit providers to file administrative appeals that would result

in a retroactive revision of prospectively determined payment rates.

(c) *Satisfactory assurances.* The State must provide to CMS satisfactory assurance as to the following:

(1) The system provides for equitable treatment of hospital patients and hospital employees.

(2) The system provides for equitable treatment of all entities that pay hospitals for inpatient hospital services, including Federal and State programs. Under the requirement, the following conditions must be met:

(i) Both the Medicare and Medicaid programs must participate under the system.

(ii) The State must assure equitable and uniform treatment under the system of third-party payors of inpatient hospital services in terms of opportunity. Equitable opportunity must include, but need not be limited to, participation in the system and availability of discounts. Criteria under which discounts are made available must be equitably and uniformly applied to all payors, except for discounts negotiated by HMOs and CMPs. Discounts available to HMOs and CMPs as result of their statutory right to negotiate payment rates independently of a State system, as described in paragraph (b)(7) of this section, need not be available to other payors.

(iii) The State must assure that all third-party payors that participate under the system share in the system's risks and benefits.

(3) The amount of Medicare payments made under the system over 36-month periods may not exceed the amount of Medicare payment that would otherwise have been made under the Medicare principles of reimbursement for Medicare items and services had the State system not been in effect. States must submit the assurance and supporting data as required by § 403.320 to document that the payment limit is not exceeded. States that have an existing Medicare demonstration project in effect on April 20, 1983, and that have requested approval of a State system under section 1886(c)(4) of the Act, may elect to have the effectiveness of the State system under this paragraph judged on the basis of the State system's rate of increase or inflation in

Medicare inpatient hospital payments as compared to the national rate of increase or inflation for such payments during the three cost reporting periods of the hospitals in the State beginning on or after October 1, 1983.

(d) *Additional cost-effectiveness assurance.* If the assurances and supporting data required under paragraph (c)(3) of this section are insufficient to provide assurance satisfactory to CMS regarding the cost-effectiveness of a State system, the State may additionally submit one of the following assurances in order to meet the cost-effectiveness test:

(1) *State responsibility for excess payments.* The State must agree that each month Medicare intermediaries will disburse to the State's hospital Federal funds that in the aggregate equal no more than would have been disbursed in the absence of the State system. Any additional funds necessary to pay hospitals for Medicare services required by the State system will be paid to the intermediaries by the State. These additional amounts will be refunded to the State by the intermediaries to the extent that, in subsequent months, the State system requires a smaller aggregate payment for Medicare services than would have been paid in the absence of the State system.

(2) *Limitations on payments.* (i) The State must agree that if its projections exceed what Medicare would pay in any particular period, the State and CMS will establish and agreed upon payment schedule that will limit payments under the State system based on a predetermined percentage relationship between projected State payments and what payments would have been under Medicare.

(ii) If deviation from the predetermined relationship described in paragraph (d)(2)(i) of this section occurs, the State must further agree that—

(A) Medicare payments would be capped automatically at payment levels based on the rates used for the Medicare prospective payment system and the State would be required to pay the difference to individual hospitals in its system; or

(B) The State may provide by legislation or legally binding regulations that

any reduced payments to hospitals under the system that result from this cost-effectiveness assurance will constitute full and final payment for hospital services furnished to Medicare beneficiaries for the period covered by these reduced payments.

**§ 403.306 Additional requirements for State systems—mandatory approval.**

(a) *General policy—(1) Mandatory approval.* HFCA will approve an application for Medicare reimbursement under a State system if the system meets all of the requirements of § 403.304 and of paragraph (b) of this section.

(2) *Exception.* CMS may approve an application if the State system meets all of the requirements of § 403.304 but only some of the requirements of paragraph (b) of this section.

(b) *Additional requirements—(1) Operation of system.* The system must—

(i) Be operated directly by the State or by entity designated under State law;

(ii) Provide for payments to hospitals using a methodology under which—

(A) Prospectively determined payment rates are established; and

(B) Exceptions, adjustments, and methods for changes in methodology are set forth;

(iii) Provide that a change by the State in the system that has the effect of materially changing payments to hospitals can take effect only upon 60 days notice to CMS and to the hospitals likely to be materially affected by the change and upon CMS's approval of the change.

(2) *Satisfactory assurances—(i) Admissions practice.* The State must assure that the operation of the system will not result in any change in hospital admission practices that result in—

(A) A significant reduction in the proportion of patients receiving hospital services covered under the system who have no third-party coverage and who are unable to pay for hospital services;

(B) A significant reduction in the proportion of individuals admitted to hospitals for inpatient hospital services for which payment is less, or is likely to be less, than the anticipated charges for or cost of the services;

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(C) A refusal to admit patients who would be expected to require unusually costly or prolonged treatment for reasons other than those related to the appropriateness of the care available at the hospital; or

(D) A refusal to provide emergency services to any person who is in need of emergency services, if the hospital provides the services.

(ii) *Consultation with local government officials.* The State must provide documentation that it has consulted with local government officials concerning the impact of the system on publicly owned or operated hospitals.

**§ 403.308 State systems under demonstration projects—mandatory approval.**

CMS will approve an application from a State for a State system if—

(a) The system was in effect prior to April 20, 1983 under an existing demonstration project; and

(b) The minimum requirements and assurances for approval of a State system are met under § 403.304 (b)(1)-(10) and § 403.304(c), and, if appropriate § 403.304(d).

**§ 403.310 Reduction in payments.**

(a) *General rule.* If CMS determines that the satisfactory assurances required of a State under § 403.304(c) and, if applicable, § 403.304(d) have not been met, or will not be met, with respect to any 36-month period, CMS will reduce Medicare payments to individual hospitals being reimbursed under the State's system or, if applicable, under the Medicare payment system, in an amount equal to the amount by which the Medicare payments under the system exceed the amount of Medicare payments to such hospitals that otherwise would have been made not using the State system. The amount of the recoupment will include, when appropriate, interest charges computed in accordance with § 405.378 of this chapter.

(b) *Recoupment procedures.* The amount of the overpayment will be recouped on a proportionate basis from each of those hospitals that received payments under the State system that exceeded the payments they would have received under the Medicare pay-

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ment system. Each hospital's share of the aggregate excess payment will be determined on the basis of a comparison of the hospital's proportionate share of the aggregate payment received under the State system that is in excess of what the aggregate payment would have been under the Medicare payment system. Recoupments may be accomplished by a hospital's direct payment to the Medicare program or by offsets to future payments made to the hospital.

(c) *Alternative recoupment procedures.* As an alternative to the recoupment procedures described in paragraph (b) of this section and subject to CMS's acceptance, the State may provide, by legislation or legally binding regulations, procedures for the recoupment of the amount of payments that exceed the amount of payments that otherwise would have been paid by Medicare if the State system had not been in effect.

(d) *Rule for existing Medicare demonstration projects.* In cases of existing Medicare demonstration projects where the expenditure test is to be applied by a rate of increase factor, the amount of the excess payment will be determined, for the three hospital cost reporting periods beginning before October 1, 1986, by a comparison of the State system's rate of increase to the national rate of increase. Recoupment of excessive payments will be assessed and recouped as described in this section.

[51 FR 15492, Apr. 24, 1986, as amended at 61 FR 63748, Dec. 2, 1996]

**§ 403.312 Submittal of application.**

The Chief Executive Officer of the State is responsible for—

(a) Submittal of the application to CMS for approval; and

(b) Supplying the assurances and necessary documentation as required under §§ 403.304 through 403.308.

**§ 403.314 Evaluation of State systems.**

CMS will evaluate all State applications for approval of State systems and notify the State of its determination within 60 days.

**§ 403.316 Reconsideration of certain denied applications.**

(a) *Request for reconsideration.* If CMS denies an application for a State system, the State may request that CMS reconsider the denial if the State believes that its system meets all of the requirements for mandatory approval under §§ 403.304 and 403.306 or, in the case of a State with a system operating under an existing demonstration project, the applicable requirements of §§ 403.304 and 403.308.

(b) *Time limit.* (1) The State must submit its request for reconsideration within 60 days after the date of CMS's notice that the application was denied.

(2) CMS will notify the State of the results of its reconsideration within 60 days after it receives the request for reconsideration.

**§ 403.318 Approval of State systems.**

(a) *Approval agreement.* If CMS approves a State system, a written agreement will be executed between CMS and the Chief Executive Officer of the State. The agreement must incorporate any terms of the State's application for approval of the system as agreed to by the parties and, as a minimum, must contain provisions that require the following:

(1) The system is operated directly by the State or an entity designated by State law.

(2) For purposes of the Medicare program, the State's system applies only to Medicare payments for inpatient, and if applicable, outpatient hospital services.

(3) The system conforms to applicable Medicare law and regulations other than those relating to the amount of reimbursement for inpatient hospital services, or for inpatient and outpatient services, whichever the State system covers. Applicable regulations include, for example, those describing Medicare benefits and entitlement requirements for program beneficiaries, as explained in parts 406 and 409 of this chapter; the requirements at part 405, subpart J of this chapter specifying conditions of participation for hospitals; the requirements at part 405, subparts A, G, and S of this chapter on Medicare program administration; and all applicable fraud and abuse regula-

tions contained in titles 42 and 45 of the CFR.

(4) The State must obtain CMS's approval of the State's reporting forms and of provider cost reporting forms or other forms that have not been approved by CMS but that are necessary for the collection of required information.

(b) *Effective date.* An approved State system may not be effective earlier than the date of the approval agreement, which may not be retroactive.

**§ 403.320 CMS review and monitoring of State systems.**

(a) *General rule.* The State must submit an assurance and detailed and quantitative studies of provider cost and financial data and projections to support the effectiveness of its system, as required by paragraphs (b) and (c) of this section.

(b) *Required information.* (1) Under § 403.304(c)(3) an assurance is required that the system will not result in greater payments over a 36-month period than would have otherwise been made under Medicare not using such system. If a State that has an existing demonstration project in effect on April 20, 1983 elects under § 403.304(c)(3) to have the effectiveness of its system judged on the basis of a rate of increase factor, the State must submit an assurance that its rate of increase or inflation in inpatient hospital payments does not exceed, for that portion of the 36-month period that is subject to this test, the national rate of increase or inflation in Medicare inpatient hospital payments. The election of the rate of increase test applies only to the three cost reporting periods beginning on or after October 1, 1983. At the end of these cost reporting periods, the State must assure, beginning with the first month after the expiration of the third cost reporting period beginning after October 1, 1983, that payments under its system will not exceed over the remainder of the 36-month period what Medicare payments would have been.

(2) Estimates and data are required to support the State's assurance, required under § 403.304(c)(3), that expenditures under the State system will not exceed what Medicare would have paid

over a 36-month period. The estimates and projections of what Medicare would have otherwise paid must take into account all the Medicare reimbursement principles in effect at the time and, for any period in which payments either exceed or are less than Medicare levels, the values of interest the Medicare Trust Fund earned, or would have earned, on these amounts. Upon application for approval, the State must submit projections for each hospital for the first 12-month period covered by the assurance, in both the aggregate and on a per discharge basis, of Medicare inpatient expenditures under Medicare principles of reimbursement and parallel projections of Medicare inpatient expenditures under the State's system and the resulting cost or savings to Medicare. The State must also submit separate statewide projections for each year of the 36-month period, in both the aggregate and on a weighted average discharge basis, of inpatient expenditures under the State system and under the Medicare principles of reimbursement.

(3) The projection submitted under paragraph (b)(2) of this section must include a detailed description of the methodology and assumptions used to derive the expenditure amounts under both systems. In instances where the assumptions are different under the projections cited in paragraph (b)(2) of this section, the State must provide a detailed explanation of the reasons for the differences. At a minimum, the following separate data and assumptions are to be included in the projections for the Medicare principles and for the State's system.

(i) The State system base year and the Medicare allowable and reimbursable cost of each hospital that the State used to develop the projections, including the amount of estimated pass through costs.

(ii) The categories of costs that are included in the State system and are reimbursed differently under the State system than under the Medicare system.

(iii) The number of Medicare and total base year discharges and admissions for each hospital.

(iv) The rate of change factor (and the method of application of this fac-

tor) used to project the base year costs over the 36-month period to which the assurance would apply.

(v) Any allowance for anticipated growth in the amount of services from the base year (if applicable, the allowance must be presented in separate estimates for population increases or for increases in rates of admissions or both).

(vi) Any adjustment in which the State is permitted by CMS to take into account previous reductions in the Medicare payment amounts that were the result of the effectiveness of the State's system even though Medicare was not a part of that system.

(vii) Appropriate recognition and projection of the time value of trust fund expenditures for the period the State system expenditures were either less than or exceeded the Medicare system payments.

(viii) States applying under a rate of increase effectiveness test under § 403.304(c)(3) must also submit data projecting the parallel rates of increase during the requisite period.

(4) The projections must include both the aggregate payments and the payments per discharge for the individual hospitals and for the State as a whole.

(5) On a case-by-case basis. CMS may require additional data and documentation as needed to complete its review and monitoring.

(6) For existing Medicare demonstration projects in effect on April 20, 1983, the assurance and data as required by paragraphs (a) and (b) of this section, if appropriate, may be based on aggregate payments or payments per inpatient admission or discharge. CMS will judge the effectiveness of these systems on the basis of the rate of increase or inflation in Medicare inpatient hospital payments compared to the national rate of increase or inflation for such payments during the State's hospitals' three cost reporting periods beginning on or after October 1, 1983. The data submitted by the State for the period subject to the rate of increase test must include the rate of increase projection for that particular period of time. For the subsequent period of time, the State must assure that payments under its system will not exceed

what Medicare payments would have been, as described in § 403.304(c)(3).

(7) If the amount of Medicare payments under the State system exceeds what would have been paid under the Medicare reimbursement principles in any given year, the State must also submit quantitative evidence that the system will result in expenditures that do not exceed what Medicare expenditures would have been over the 36 month period beginning with the first month that the State system is operating. For a State that has an existing demonstration project in effect on April 20, 1983, and that elects under § 403.304(c)(3) to have a rate of increase test apply, if the State's rate of increase or inflation exceeds the national rate of increase or inflation in a given year, the State must submit quantitative evidence that, over 36 months, its payments will not exceed the national rate of increase or inflation. Furthermore, if payments under the State's system must be compared to actual Medicare expenditures, at the end of the third cost reporting period, as described in paragraph (b)(1) of this section, and payments under the State's system exceed what Medicare would have paid in a given year, the State must submit quantitative evidence that, over 36 months, payments under its system will not exceed what Medicare would have paid.

(c) *Review of assurances regarding expenditures.* CMS will review the State's assurances and data submitted under this section, as a prerequisite to the approval of the State's system. CMS will compare the State's projections of payment amounts to CMS data in order to determine if the State's assurance is reasonable and fully supportable. If the CMS data indicate that the State's system would result in payment amounts that would be more than that which would have been paid under the Medicare principles, the State's assurances would not be acceptable. For States applying in accordance with § 403.308, if CMS data indicate that the State's system would result in a rate of increase or inflation that would be more than the national rate of increase or inflation, the State's assurances would not be acceptable.

(d) *Medicaid upper limit.* In accordance with § 447.253 of this chapter, the State system may not result in aggregate payments for Medicaid inpatient hospital services that would exceed the amount that would have otherwise have been paid under the Medicare principles as applied through the State system.

(e) *Monitoring of Medicare expenditures.* CMS will monitor on a quarterly basis expenditures under the State's system as compared to what Medicare expenditures would have been if the system had not been in effect. If CMS determines at any time that the payments made under the State's system exceed the States' projections, as established by the satisfactory assurances required under § 403.304(c) and, if appropriate, the predetermined percentage relationship of the payments as required under § 403.304(d). CMS will—

(1) Conclude that payments under the State system over a 36-month period will exceed what Medicare would have paid;

(2) Terminate the waiver; and

(3) Recoup overpayments to the affected hospitals in accordance with the procedures described in § 403.310.

**§ 403.321 State systems for hospital outpatient services.**

CMS may approve a State's application for approval of an outpatient system if the following conditions are met:

(a) The State's inpatient system is approved.

(b) The State's outpatient application meets the requirements and assurances for an inpatient system described in § 403.304 (b) and (c), and § 403.306 (b)(1) and (b)(2)(ii).

(c) The State submits a separate application that provides separate assurances and estimates and data in further support of its assurance submitted under paragraph (b)(1) of § 403.320, as follows:

(1) Upon application for approval, the State must submit estimates and data that include, but are not limited to, projections for the first 12-month period covered by the assurance for each hospital, in both the aggregate and on

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an average cost per service and payment basis, of Medicare outpatient expenditures under Medicare principles of reimbursement; parallel projections of Medicare outpatient expenditures under the State system; and the resulting cost or savings to Medicare independent of the State system for hospital inpatient services.

(2) The State must submit separate statewide projections for each year of the 36-month period of the aggregate outpatient expenditures for each system. The projections submitted under this paragraph must—

(i) Comply with the requirements of paragraphs (b) (3) and (5) of § 403.320 regarding a detailed description of the methodology used to derive the expenditure amounts;

(ii) Include the data and assumptions set forth in paragraphs (b)(3) (i), (ii), (iii), (iv), and (v) of § 403.320; and

(iii) Include any assumption the State has adopted for establishing the number of Medicare and total base year outpatient services for each hospital.

(3) The State must provide a detailed explanation of the reasons for any difference between the data or assumptions used for the separate projections.

### **§ 403.322 Termination of agreements for Medicare recognition of State systems.**

(a) *Termination of agreements.* (1) CMS may terminate any approved agreement if it finds, after the procedures described in this paragraph are followed that the State system does not satisfactorily meet the requirements of section 1886(c) of the Act or the regulations in this subpart. A termination must be effective on the last day of a calendar quarter.

(2) CMS will give the State reasonable notice of the proposed termination of an agreement and of the reasons for the termination at least 90 days before the effective date of the termination.

(3) CMS will give the State the opportunity to present evidence to refute the finding.

(4) CMS will issue a final notice of termination upon a final review and determination on the State's evidence.

(b) *Termination by State.* A State may voluntarily terminate a State system by giving CMS notice of its intent to

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terminate. A termination must be effective on the last day of a calendar quarter. The State must notify CMS of its intent to terminate at least 90 days before the effective date of the termination.

### **Subpart D [Reserved]**

### **Subpart E—Beneficiary Counseling and Assistance Grants**

SOURCE: 59 FR 51128, Oct. 7, 1994, unless otherwise noted.

#### **§ 403.500 Basis, scope, and definition.**

(a) *Basis.* This subpart implements, in part, the provisions of section 4360 of Public Law 101-508 by establishing a minimum level of funding for grants made to States for the purpose of providing information, counseling, and assistance relating to obtaining adequate and appropriate health insurance coverage to individuals eligible to receive benefits under the Medicare program.

(b) *Scope of subpart.* This subpart sets forth the following:

(1) Conditions of eligibility for the grant.

(2) Minimum levels of funding for those States qualifying for the grants.

(3) Reporting requirements.

(c) *Definition.* For purposes of this subpart, the term “State” includes (except where otherwise indicated by the context) the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, and American Samoa.

#### **§ 403.501 Eligibility for grants.**

To be eligible for a grant under this subpart, the State must have an approved Medicare supplemental regulatory program under section 1882 of the Act and submit a timely application to CMS that meets the requirements of—

(a) Section 4360 of Public Law 101-508 (42 USC 1395b-4);

(b) This subpart; and

(c) The applicable solicitation for grant applications issued by CMS.

**§ 403.502 Availability of grants.**

CMS awards grants to States subject to availability of funds, and if applicable, subject to the satisfactory progress in the State's project during the preceding grant period. The criteria by which progress is evaluated and the performance standards for determining whether satisfactory progress has been made are specified in the terms and conditions included in the notice of grant award sent to each State. CMS advises each State as to when to make application, what to include in the application, and provides information as to the timing of the grant award and the duration of the grant award. CMS also provides an estimate of the amount of funds that may be available to the State.

[65 FR 34985, June 1, 2000]

**§ 403.504 Number and size of grants.**

(a) *General.* For available grant funds, up to and including \$10,000,000, grants will be made to States according to the terms and formula in paragraphs (b) and (c) of this section. For any available grant funds in excess of \$10,000,000, distribution of grants will be at the discretion of CMS, and will be made according to criteria that CMS will communicate to the States via grant solicitation. CMS will provide information to each State as to what must be included in the application for grant funds. CMS awards the following type of grants:

(1) New program grants.

(2) Existing program enhancement grants.

(b) *Grant Award.* Subject to the availability of funds, each eligible State that submits an acceptable application receives a grant that includes a fixed amount (minimum funding level) and a variable amount.

(1) A fixed portion is awarded to States in the following amounts:

(i) Each of the 50 States, \$75,000.

(ii) The District of Columbia, \$75,000.

(iii) Puerto Rico, \$75,000.

(iv) American Samoa, \$25,000.

(v) Guam, \$25,000.

(vi) The Virgin Islands, \$25,000.

(2) A variable portion, which is based on the number and location of Medicare beneficiaries residing in the State

is awarded to each State. The variable amount a particular State receives is determined as set forth in paragraph (c) of this section.

(c) *Calculation of variable portion of the grant.* (1) CMS bases the variable portion of the grant on—

(i) The amount of available funds, and

(ii) A comparison of each State with the average of all of the States (except the State being compared) with respect to three factors that relate to the size of the State's Medicare population and where that population resides.

(2) The factors CMS uses to compare States' Medicare populations comprise separate components of the variable amount. These factors, and the extent to which they each contribute to the variable amount, are as follows:

(i) Approximately 75 percent of the variable amount is based on the number of Medicare beneficiaries living in the State as a percentage of all Medicare beneficiaries nationwide.

(ii) Approximately 10 percent of the variable amount is based on the percentage of the State's total population who are Medicare beneficiaries.

(iii) Approximately 15 percent of the variable amount is based on the percentage of the State's Medicare beneficiaries that reside in rural areas ("rural areas" are defined as all areas not included within a Metropolitan Statistical Area).

(3) Based on the foregoing four factors (that is, the amount of available funds and the three comparative factors), CMS determines a variable rate for each participating State for each grant period.

(d) *Submission of revised budget.* A State that receives an amount of grant funds under this subpart that differs from the amount requested in the budget submitted with its application must submit a revised budget to CMS, along with its acceptance of the grant award, that reflects the amount awarded.

[59 FR 51128, Oct. 7, 1994, as amended at 65 FR 34986, June 1, 2000]

**§ 403.508 Limitations.**

(a) *Use of grants.* Except as specified in paragraph (b) of this section, and in the terms and conditions in the notice

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of grant award, a State that receives a grant under this subpart may use the grant for any reasonable expenses for planning, developing, implementing, and/or operating the program for which the grant is made as described in the solicitation for application for the grant.

(b) *Maintenance of effort.* A State that receives a grant to supplement an existing program (that is, an existing program enhancement grant)—

(1) Must not use the grant to supplement funds for activities that were conducted immediately preceding the date of the initial award of a grant made under this subpart and funded through other sources (including in-kind contributions).

(2) Must maintain the activities of the program at least at the level that those activities were conducted immediately preceding the initial award of a grant made under this subpart.

[59 FR 51128, Oct. 7, 1994, as amended at 65 FR 34986, June 1, 2000]

### § 403.510 Reporting requirements.

A State that receives a grant under this subpart must submit at least one annual report to CMS and any additional reports as CMS may prescribe in the notice of grant award. CMS advises the State of the requirements concerning the frequency, timing, and contents of reports in the notice of grant award that it sends to the State.

### § 403.512 Administration.

(a) *General.* Administration of grants will be in accordance with the provisions of this subpart, 45 CFR part 92 ("Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments"), 45 CFR 74.4, the terms of the solicitation, and the terms of the notice of grant award. Except for the minimum funding levels established by § 403.504(b)(1), in the event of conflict between a provision of the notice of grant award, any provision of the solicitation, or of any regulation enumerated in 45 CFR 74.4 or in part 92, the terms of the notice of grant award control.

(b) *Notice.* CMS provides notice to each applicant regarding CMS's deci-

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sion on an application for grant funding under § 403.504.

(c) *Appeal.* Any applicant for a grant under this subpart has the right to appeal CMS's determination regarding its application. Appeal procedures are governed by the regulations at 45 CFR part 16 (Procedures of the Departmental Grant Appeals Board).

### Subpart F [Reserved]

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

SOURCE: 64 FR 67047, Nov. 30, 1999, unless otherwise noted.

### § 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 CMS may require to implement section 1821 of the Act, including information relating to quality of care and coverage decisions.

(10) Meets other requirements CMS 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 CMS 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.

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(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 CMS.

(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 RNHCI.

(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 CMS 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 CMS in writing.

(2) The receipt of excepted medical treatment as defined in § 403.702 does

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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) CMS 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

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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 RNHCI's.

(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 CMS 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.

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(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) CMS 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 otherwise provided in this section, the RNHCI must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes. Chapter 19.3.6.3.2, exception number 2 of the adopted Life Safety Code does not apply to an RNHCI.

(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 paragraph (a)(1) of this section would result in unreasonable hardship upon the RNHCI, CMS 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 CMS 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.

(c) *Phase-in period.* An RNHCI must be in compliance with the following provisions beginning on March 13, 2006:

(1) Chapter 19.3.6.3.2, exception number 2.

(2) Chapter 19.2.9, Emergency Lighting.

[64 FR 67047, Nov. 30, 1999, as amended at 68 FR 1385, Jan. 10, 2003]

**§ 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.* CMS 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 RNHCI's will be reduced by a proportional percentage to prevent estimated expenditures from exceeding the trigger level. In addition to reducing payments proportionally, CMS may impose alternative adjustments.

(c) *Notification of adjustments.* CMS notifies participating RNHCI's 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 RNHCI's.* 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).

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**§ 403.754 Monitoring expenditure level.**

(a) *Tracking expenditures.* Starting in FFY 1999 CMS 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, CMS 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.

**Subpart H—Medicare-Endorsed Prescription Drug Card Assistance Initiative**

SOURCE: 67 FR 56682, Sept. 4, 2002, unless otherwise noted.

**§ 403.800 Basis and scope.**

(a) *Provisions of the legislation.* This subpart implements, in part, the provisions of section 4359 of the Omnibus Budget Reconciliation Act of 1990 (OBRA). Section 4359 of OBRA requires the Secretary to establish a health insurance advisory service program (the beneficiary assistance program) to assist Medicare beneficiaries with the receipt of services (including both covered and uncovered benefits) under the Medicare and Medicaid programs and other health insurance programs. The

subpart is also based on sections 1102 and 1871 of the Act.

(b) *Scope of subpart.* This subpart sets forth the standards and procedures CMS uses to implement the Medicare-Endorsed Prescription Drug Card Assistance Initiative.

**§ 403.802 Definitions.**

*For purposes of this subpart, the following definitions apply:*

*Administrative consortium* means a private entity established and financed by the Medicare-endorsed prescription drug card program sponsors to carry out a set of specific administrative tasks required under the Medicare-Endorsed Prescription Drug Card Assistance Initiative.

*Applicant* means the organization or entity (along with any subcontractors or others with whom it has legal arrangements for the purpose of meeting the requirements for endorsement) that is applying for Medicare endorsement of its prescription drug discount card program.

*Application* means the document submitted to CMS by an applicant that demonstrates compliance with the requirements specified in this subpart in order to obtain Medicare endorsement of the applicant's drug card program.

*Formulary* means the list of specific drugs for which the Medicare-endorsed prescription drug card program offers discounts to Medicare beneficiaries enrolled in the Medicare-endorsed prescription drug card program.

*Medicare-Endorsed Prescription Drug Card Assistance Initiative* means an effort whereby CMS provides information, counseling, and assistance to Medicare beneficiaries by soliciting applications for Medicare endorsement of prescription drug card programs, reviewing them, offering agreements to program sponsors that meet all of the requirements for endorsement, awarding Medicare endorsements to program sponsors who sign the agreement, and educating beneficiaries about the options available to them in the private marketplace.

*Medicare-endorsed prescription drug card program* means a program developed by an organization or group of organizations, endorsed by CMS under the Medicare-Endorsed Prescription

Drug Card Assistance Initiative, to educate Medicare beneficiaries about tools to lower their prescription drug costs and to offer prescription drug discount cards to Medicare beneficiaries.

*Medicare-endorsed prescription drug card program sponsor* means any applicant that has received endorsement from Medicare for its prescription drug card program.

*Solicitation* means a notice published in the FEDERAL REGISTER announcing a request for applications from applicants seeking Medicare endorsement for their prescription drug card programs.

**§ 403.804 General rules for Medicare endorsement.**

(a) *Applications.* Applicants must submit applications by the deadline announced in the solicitation to participate in the Medicare-Endorsed Prescription Drug Card Assistance Initiative and become a Medicare-endorsed prescription drug card program sponsor.

(b) *Number of programs sponsored.* An organization or entity may sponsor no more than two drug card programs. The same organization or entity may have operational responsibilities in multiple drug card programs.

(c) *Requirements.* In order to be eligible for endorsement, applicants must submit applications and meet all of the requirements specified in § 403.806.

(d) *Eligibility to receive endorsement.* Any applicant that submits an application by the deadline announced in the solicitation that contains all information necessary for CMS to determine whether the applicant meets all of the requirements in § 403.806, and whose application meets all of the requirements in § 403.806, will be eligible to enter into an agreement with CMS to receive a Medicare endorsement.

(e) *Period of endorsement.* In Year One of the initiative, the Medicare endorsement will be effective for a period of at least 12 months but fewer than 24 months. Beginning in Year Two, the endorsement will be effective at least 12 months, but fewer than 15 months. CMS will consider card program sponsor performance under an existing Medicare endorsement as a factor in

determining eligibility for endorsement in future annual cycles.

(f) *Termination of endorsement by CMS.* CMS may terminate the endorsement at any time.

(g) *Termination of participation by Medicare-endorsed drug card sponsor.* A Medicare-endorsed prescription drug card program sponsor may choose not to continue participation in the Medicare-Endorsed Prescription Drug Card Assistance Initiative.

(h) *Notification to beneficiaries of termination of participation.* (1) In the event of termination of participation in the initiative by the drug card program sponsor, or termination by CMS, the Medicare-endorsed prescription drug card program sponsor must notify all of its Medicare beneficiary enrollees in writing that they may enroll in an alternative Medicare-endorsed prescription drug card program. This notice must be provided by United States mail within 10 days of providing CMS with notice of termination or within 10 days of receiving notice of termination from CMS.

(2) In the event of termination by the drug card program sponsor, or termination by CMS, drug card programs must remain available to beneficiaries for 90 days after beneficiaries are provided with notice of termination. In the event of termination by the drug card program sponsor, or termination by CMS, drug card program sponsors must suspend information and outreach and enrollment of beneficiaries once beneficiaries have been notified of the termination.

**§ 403.806 Requirements for eligibility for endorsement.**

(a) *General.* To be eligible for Medicare endorsement, an applicant must submit an application by the deadline announced in the solicitation, demonstrating that it meets and will comply with the requirements described in this section.

(b) *Applicant structure, experience, and participation in administrative consortium.* (1) A single organization or entity that is either the applicant or a subcontractor or under other legal arrangement with the applicant must have no less than 3 years experience in

pharmacy benefit management, in administering a prescription drug discount program, or in administering a low income drug assistance program that provides prescription drugs at low or no cost;

(2) A single organization or entity that is either the applicant or a subcontractor or under other legal arrangement with the applicant must, at the time of application for endorsement, manage at least 1 million covered lives in an insured pharmacy benefit, prescription drug discount program, or a low income drug assistance program that provides prescription drugs at low or no cost.

(3) A single organization or entity that is either the applicant or a subcontractor or under other legal arrangement with the applicant must—

(i) Have a pharmacy network serving all 50 States and the District of Columbia to qualify as a national program; or

(ii) Have a regional pharmacy network serving at least 2 contiguous States (with the exception of Hawaii and Alaska, which can partner with 2 or more contiguous States) to qualify as a regional program.

(4) The applicant must demonstrate that it is financially solvent.

(5) The applicant must have a satisfactory record of integrity and business ethics.

(6) The applicant must agree to, and demonstrate the ability to, jointly administer, abide by the guidelines of, and fund a private administrative consortium with other Medicare-endorsed prescription drug card program sponsors in accordance with the requirements of this subpart.

(7) The applicant must comply with all applicable Federal and State laws.

(c) *Customer service.* The applicant must comply with the following customer service requirements:

(1) Limit its one time enrollment fee in Year One to no more than \$25. In future years, CMS may adjust the fee based on a determination of what is a reasonable amount to defray costs of the applicant's administrative activities.

(2) Enroll only Medicare beneficiaries, and all Medicare beneficiaries who wish to participate in its Medi-

care-endorsed prescription drug card program.

(3) Provide information and outreach materials regarding its Medicare-endorsed prescription drug card program to all enrolled Medicare beneficiaries.

(4) Maintain a toll free customer call center that is open during usual business hours and that provides customer telephone service, including to pharmacists, in accordance with standard business practices.

(d) *Privacy and confidentiality of beneficiary-specific information.* (1) The applicant must comply, beginning at the time of Medicare endorsement, with 45 CFR 160.103, 160.202, 164.501 through 164.514, and 164.520, subject to the following modifications:

(i) All references to covered entities will be applicable to the drug card sponsor, and health care operations means the routine activities, including providing information and outreach, as provided under the Medicare endorsement; and

(ii) For the purpose of authorization in 45 CFR 164.508, marketing means any use or disclosure of protected health information to be outside the scope of Medicare endorsement.

(2) The applicant must develop and implement a written data security plan for protected health information.

(3) The requirements of this paragraph (d) are enforceable by CMS under the provisions of § 403.812.

(4) Nothing in this paragraph (d) modifies the applicability of 45 CFR 160.103, 160.202, 164.501 through 164.514, and 164.520 to organizations or entities independently subject to the mandates of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

(e) *Discounts, rebates, and access.* The applicant must comply with the following discount, rebate, and access requirements:

(1) Offer a discount on at least one brand name or generic prescription drug in each of the therapeutic drug classes, groups, or subgroups representing the prescription drugs commonly needed by Medicare beneficiaries.

(2) Obtain pharmaceutical manufacturer drug rebates or discounts on brand name or generic drugs or both,

and ensure that a substantial share is provided to beneficiaries either directly or indirectly through pharmacies.

(3) Ensure that a specific drug offered under the program is not dropped from the formulary nor its price increased for periods of at least 60 days, starting on the first day of the program's operation, and notify CMS, the consortium, and the network pharmacies of these changes 30 days before the change becomes effective.

(4) Guarantee that for the drugs for which the applicant will offer discounts, Medicare beneficiaries enrolled in its Medicare-endorsed prescription drug discount card program will receive the lower of the discounted price available through the program, or the price the pharmacy would charge a cash paying customer.

(5) Have a national or regional contracted pharmacy network sufficient to ensure that pharmacies are locally accessible to beneficiaries where the drug discount card will be offered. At least 90 percent of Medicare beneficiaries, on average, in all Metropolitan Statistical Areas (MSAs) served by the program must live within 5 miles of a contracted pharmacy; and at least 90 percent of Medicare beneficiaries, on average, in all non-MSAs served by the program must live within 10 miles of a contracted pharmacy.

(6) Provide to the administrative consortium information on drugs and their pricing included in the applicant's formularies.

**§ 403.807 Application process.**

(a) CMS will solicit applications through an application process.

(b) CMS will review applications and determine whether the applicant has met and is able to comply with all of the requirements set forth in § 403.806 to become Medicare-endorsed.

(c) All applications that are submitted by the deadline announced in the solicitation and that demonstrate that the applicant has met and is able to comply with all of the requirements to become Medicare-endorsed will be eligible to enter into an agreement to receive Medicare endorsement from CMS.

**§ 403.808 Agreement terms and conditions.**

In order to receive a Medicare endorsement, an applicant that complies with all of the application procedures and meets all of the requirements described in this subpart must enter into a written agreement with CMS. The agreement must include a statement by the applicant that it has met the requirements of this subpart and will continue to meet all requirements as long as the agreement is in effect. The agreement must include a statement that the applicant will comply with information and outreach guidelines established by CMS.

**§ 403.810 Administrative consortium responsibilities and oversight.**

(a) The administrative consortium will be responsible for—

(1) Ensuring that beneficiaries are not enrolled in more than one Medicare-endorsed prescription drug card program at the same time;

(2) Facilitating the publication of, or publishing, information, including comparative price information on discounted drugs, that assists beneficiaries in determining which Medicare-endorsed prescription drug card program is the most appropriate for their needs;

(3) Ensuring the integrity of the information distributed by the Medicare-endorsed prescription drug card programs; and

(4) Developing and implementing a written data security plan for protected health information; and

(5) Abiding by applicable Federal and State laws.

(b) In order to facilitate the formation of the administrative consortium and ensure that all functions are performed in a timely manner, CMS may assist in the start-up of the administrative consortium and perform any of the functions in this section for a transitional period of time.

**§ 403.811 Beneficiary enrollment.**

(a) *Individual enrollment.* (1) Medicare beneficiaries who are enrolling in a Medicare-endorsed prescription drug card program for the first time may enroll at any time.

**§ 403.812**

(2) Once enrolled, a Medicare beneficiary may belong to only one Medicare-endorsed prescription drug card program at a time.

(3) Once enrolled, and except as provided in paragraph (a)(4) of this section, enrollees may change enrollment to a different Medicare-endorsed prescription drug card program, to be effective the first day of the following January or July following the request for change, whichever comes first.

(4) If the Medicare endorsement of a prescription drug card program is terminated, either by CMS or by the sponsor, enrolled Medicare beneficiaries may enroll in a different Medicare-endorsed prescription drug card program to become effective immediately.

(b) *Group enrollment.* (1) The prescription drug card program sponsor may accept group enrollment from health insurers and must ensure—

(i) Disclosure to Medicare beneficiaries of the intent to enroll them as a group;

(ii) Disclosure to beneficiaries of the enrollment exclusivity restrictions and other enrollment rules of the initiative;

(2) Medicare+Choice (M+C) organizations may subsidize the enrollment fee and offer the drug card program as part of their Adjusted Community Rate filing, but may not require enrollment in a drug card program as a condition of enrollment in any of their M+C plans.

**§ 403.812 Withdrawal of endorsement.**

If CMS obtains evidence that a Medicare-endorsed prescription drug card

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program or its sponsor has failed to meet any of the requirements for endorsement or has not complied with the agreement necessary to receive endorsement under this subpart, CMS may withdraw the endorsement. CMS may also take appropriate intermediate actions and may also refer the card program sponsor to appropriate Federal or State authorities, including the Office of Inspector General, for sanctions or prosecution under section 1140 of the Act.

**§ 403.820 Oversight and beneficiary education.**

(a) The Medicare-endorsed prescription drug card program sponsor must report to CMS on a periodic basis on major features of its programs that correspond to the qualifications for endorsement, including savings to beneficiaries, customer service, and discount card program operations. Card program sponsors must certify the validity of their reported data.

(b) The Medicare-endorsed prescription drug card program sponsor must establish and maintain a customer complaints process. This process must be designed to track and address in a timely manner enrollees' complaints about any aspect of the drug card program.

(c) CMS will conduct beneficiary education about, and oversight of, the Medicare-endorsed prescription drug card programs, as determined by CMS.