

Centers for Medicare & Medicaid Services, HHS

§ 403.205

- 403.814 Special rules concerning Part C organizations and Medicare cost plans and their enrollees.
- 403.815 Special rules concerning States.
- 403.816 Special rules concerning long-term care and I/T/U pharmacies.
- 403.817 Special rules concerning the territories.
- 403.820 Sanctions, penalties, and termination.
- 403.822 Reimbursement of transitional assistance and associated sponsor requirements.

Subpart I—Transparency Reports and Reporting of Physician Ownership or Investment Interests

- 403.900 Purpose and scope.
- 403.902 Definitions.
- 403.904 Reports of payments or other transfers of value.
- 403.906 Reports of physician ownership and investment interests.
- 403.908 Procedures for electronic submission of reports.
- 403.910 Delayed publication for payments made under product research or development agreements and clinical investigations.
- 403.912 Penalties for failure to report.
- 403.914 Preemption of State laws.

Subpart K—Access to Identifiable Data for the Center for Medicare and Medicaid Models

- 403.1100 Purpose and scope.
- 403.1105 Definitions.
- 403.1110 Evaluation of models.

Subpart L—Requirements for Direct-to-Consumer Television Advertisements of Drugs and Biological Products To Include the List Price of That Advertised Product

- 403.1200 Scope.
- 403.1201 Definitions.
- 403.1202 Pricing information.
- 403.1203 Specific presentation requirements.
- 403.1204 Compliance.

AUTHORITY: 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 (e) of this section, Medicare supplemental (or Medigap) policy means a health insurance policy or other health benefit plan that—

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

(2) 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

§ 403.206

program because of deductibles, coinsurance, or other limitations under Medicare.

(b) The term policy includes both policy form and policy as specified in paragraphs (b)(1) and (b)(2) of this section.

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

(2) *Policy.* Policy is the contract—

- (i) Issued under the policy form; and
- (ii) Held by the policy holder.

(c) If the policy otherwise meets the definition in this section, a Medicare supplemental policy includes—

- (1) An individual policy;
- (2) A group policy;
- (3) A rider attached to an individual or group policy; or

(4) As of January 1, 2006, a stand-alone limited health benefit plan or policy that supplements Medicare benefits and is sold primarily to Medicare beneficiaries.

(d) Any rider attached to a Medicare supplemental policy becomes an integral part of the basic policy.

(e) Medicare supplemental policy does not include a Medicare Advantage plan, a Prescription Drug Plan under Part D, or any of the other types of health insurance policies or health benefit plans that are excluded from the definition of a Medicare supplemental policy in section 1882(g)(1) of the Act.

[70 FR 4525, Jan. 28, 2005]

§ 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

(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

42 CFR Ch. IV (10–1–24 Edition)

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.

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'

§ 403.235

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 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

42 CFR Ch. IV (10–1–24 Edition)

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.

(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 insuring 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 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 organization 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.