

essential specialized services in the Medicare community.

Sole community physician has the same meaning as that term is defined § 1001.2 of this title.

Sole source of essential specialized services in the community has the same meaning as that term defined by the § 1001.2 of this title.

(c) *General rule.* If CMS determines that a hardship as defined in paragraph (b)(2) of this section results from exclusion of an affected person from the Medicare program, CMS may consider and may make a request to the Inspector General for waiver of the Medicare exclusion.

(d) *Submission and content of a waiver of exclusion request.* An excluded person must submit a request for waiver of exclusion in writing to CMS that includes the following:

(1) A copy of the exclusion notice from the OIG.

(2) A statement requesting that CMS present a waiver of exclusion request to the OIG on his or her behalf.

(3) A statement that he or she is the sole community physician or sole source of essential specialized services in the community.

(4) Documentation to support the statement in paragraph (d)(3) of this section.

(e) *Processing of waiver of exclusion requests.* CMS processes a request for a waiver of exclusion as follows:

(1) Notifies the submitter that the waiver of exclusion request has been received.

(2) Reviews and validates all submitted documents.

(3) During its analysis, CMS may require additional, specific information, and authorization to obtain information from private health insurers, peer review organizations (including, but not limited to, Quality Improvement Organizations), and others as necessary to determine validity.

(4) Makes a determination regarding whether or not to submit the waiver of exclusion request to the OIG based on review and validation of the submitted documents.

(5) If CMS elects to submit the waiver of exclusion request to the OIG, CMS copies the excluded person on the request.

(6) If CMS denies the request, then CMS notifies the excluded person of the decision and specifies the reason(s) for the decision.

(f) *Administrative or judicial review.* A determination rendered under paragraph (e)(4) of this section is not subject to administrative or judicial review.

PART 403—SPECIAL PROGRAMS AND PROJECTS

Subpart A [Reserved]

Subpart B—Medicare Supplemental Policies

Sec.

403.200 Basis and scope.

GENERAL PROVISIONS

403.201 State regulation of insurance policies.

403.205 Medicare supplemental policy.

403.206 General standards for Medicare supplemental policies.

403.210 NAIC model standards.

403.215 Loss ratio standards.

STATE REGULATORY PROGRAMS

403.220 Supplemental Health Insurance Panel.

403.222 State with an approved regulatory program.

VOLUNTARY CERTIFICATION PROGRAM: GENERAL PROVISIONS

403.231 Emblem.

403.232 Requirements and procedures for obtaining certification.

403.235 Review and certification of policies.

403.239 Submittal of material to retain certification.

403.245 Loss of certification.

403.248 Administrative review of CMS determinations.

VOLUNTARY CERTIFICATION PROGRAM: LOSS RATIO PROVISIONS

403.250 Loss ratio calculations: General provisions.

403.251 Loss ratio date and time frame provisions.

403.253 Calculation of benefits.

403.254 Calculation of premiums.

403.256 Loss ratio supporting data.

403.258 Statement of actuarial opinion.

Subpart C—Recognition of State Reimbursement Control Systems

403.300 Basis and purpose.

403.302 Definitions.

Centers for Medicare & Medicaid Services, HHS

Pt. 403

- 403.304 Minimum requirements for State systems—discretionary approval.
- 403.306 Additional requirements for State systems—mandatory approval.
- 403.308 State systems under demonstration projects—mandatory approval.
- 403.310 Reduction in payments.
- 403.312 Submittal of application.
- 403.314 Evaluation of State systems.
- 403.316 Reconsideration of certain denied applications.
- 403.318 Approval of State systems.
- 403.320 CMS review and monitoring of State systems.
- 403.321 State systems for hospital outpatient services.
- 403.322 Termination of agreements for Medicare recognition of State systems.

Subparts D—F [Reserved]

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

- 403.700 Basis and purpose.
- 403.702 Definitions and terms.
- 403.720 Conditions for coverage.
- 403.724 Valid election requirements.
- 403.730 Condition of participation: Patient rights.
- 403.732 Condition of participation: Quality assessment and performance improvement.
- 403.734 Condition of participation: Food services.
- 403.736 Condition of participation: Discharge planning.
- 403.738 Condition of participation: Administration.
- 403.740 Condition of participation: Staffing.
- 403.742 Condition of participation: Physical environment.
- 403.744 Condition of participation: Life safety from fire.
- 403.745 Condition of participation: Building Safety.
- 403.746 Condition of participation: Utilization review.
- 403.748 Condition of participation: Emergency preparedness.
- 403.750 Estimate of expenditures and adjustments.
- 403.752 Payment provisions.
- 403.754 Monitoring expenditure level.
- 403.756 Sunset provision.
- 403.764 Basis and purpose of religious non-medical health care institutions providing home service.
- 403.766 Requirements for coverage and payment of RNHCI home services.
- 403.768 Excluded services.

- 403.770 Payments for home services.

Subpart H—Medicare Prescription Drug Discount Card and Transitional Assistance Program

- 403.800 Basis and scope.
- 403.802 Definitions.
- 403.804 General rules for solicitation, application and Medicare endorsement period.
- 403.806 Sponsor requirements for eligibility for endorsement.
- 403.808 Use of transitional assistance funds.
- 403.810 Eligibility and reconsiderations.
- 403.811 Enrollment, disenrollment, and associated endorsed sponsor requirements.
- 403.812 HIPAA privacy, security, administrative data standards, and national identifiers.
- 403.813 Marketing limitations and record retention requirements.
- 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.

§ 403.200

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.

42 CFR Ch. IV (10–1–23 Edition)

(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 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