

SUBCHAPTER A—GENERAL PROVISIONS

PART 400—INTRODUCTION; DEFINITIONS

Subpart A [Reserved]

Subpart B—Definitions

Sec.	
400.200	General definitions.
400.202	Definitions specific to Medicare.
400.203	Definitions specific to Medicaid.

Subpart C [Reserved]

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

Subpart A [Reserved]

Subpart B—Definitions

§ 400.200 General definitions.

In this chapter, unless the context indicates otherwise—

Act means the Social Security Act, and titles referred to are titles of that Act.

Administrator means the Administrator, Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA).

ALJ stands for administrative law judge.

Area means the geographical area within the boundaries of a State, or a State or other jurisdiction, designated as constituting an area with respect to which a Professional Standards Review Organization or a Utilization and Quality Control Peer Review Organization has been or may be designated.

Beneficiary means a person who is entitled to Medicare benefits and/or has been determined to be eligible for Medicaid.

CMP stands for competitive medical plan.

Conditions of participation includes requirements for participation as the latter term is used in part 483 of this chapter.

Condition level deficiencies includes deficiencies with respect to “level A requirements” as the latter term is used in parts 442 and 483 of this chapter.

CORF stands for comprehensive outpatient rehabilitation facility.

CFR stands for Code of Federal Regulations.

CMS stands for Centers for Medicare & Medicaid Services, formerly the Health Care Financing Administration (HCFA).

CY stands for calendar year.

DAB stands for Departmental Appeals Board.

Department means the Department of Health and Human Services (HHS), formerly the Department of Health, Education, and Welfare.

ESRD stands for end-stage renal disease.

FDA stands for the Food and Drug Administration.

FQHC means Federally qualified health center.

FR stands for FEDERAL REGISTER.

FY stands for fiscal year.

HCPP stands for health care prepayment plan.

HHS stands for the Department of Health and Human Services.

HHA stands for home health agency.

HMO stands for health maintenance organization.

ICF stands for intermediate care facility.

ICF/IID stands for intermediate care facility for individuals with intellectual disabilities.

Medicaid means medical assistance provided under a State plan approved under title XIX of the Act.

Medicare means the health insurance program for the aged and disabled under title XVIII of the Act.

NCD stands for national coverage determination.

OASDI stands for the Old Age, Survivors, and Disability Insurance program under title II of the Act.

OIG stands for the Department’s Office of the Inspector General.

QDWI stands for Qualified Disabled and Working Individual.

QIO stands for quality improvement organization.

QMB stands for Qualified Medicare Beneficiary.

Qualified Disabled and Working Individual means an individual who—

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(1) Is eligible to enroll for Medicare Part A under section 1818A of the Act.

(2) Has income, as determined in accordance with SSI methodologies, that does not exceed 200 percent of the Federal poverty guidelines (as defined and revised annually by the Office of Management and Budget) for a family of the size of the individual's family;

(3) Has resources, as determined in accordance with SSI methodologies, that do not exceed twice the relevant maximum amount established, for SSI eligibility, for an individual or for an individual and his or her spouse; and

(4) Is not otherwise eligible for Medicaid.

Qualified Medicare Beneficiary means an individual who—

(1) Is entitled to Medicare Part A, with or without payment of premiums, but is not entitled solely because he or she is eligible to enroll as a QDWI;

(2) Has resources, as determined in accordance with SSI methodologies, that do not exceed twice the maximum amount established for SSI eligibility; and

(3) Has income, as determined in accordance with SSI methodologies, that does not exceed 100 percent of the Federal poverty guidelines.

Quality improvement organization means an organization that has a contract with CMS, under part B of title XI of the Act, to perform utilization and quality control review of the health care furnished, or to be furnished, to Medicare beneficiaries.

Regional Administrator means a Regional Administrator of CMS.

Regional Office means one of the regional offices of CMS.

RHC stands for rural health clinic.

RRB stands for Railroad Retirement Board.

Secretary means the Secretary of Health and Human Services.

SNF stands for skilled nursing facility.

Social security benefits means monthly cash benefits payable under section 202 or 223 of the Act.

SSA stands for Social Security Administration.

United States means the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Is-

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lands, Guam, American Samoa, and the Northern Mariana Islands.

U.S.C. stands for United States Code.

[48 FR 12534, Mar. 25, 1983]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 400.200, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and at www.fdsys.gov.

§ 400.202 Definitions specific to Medicare.

As used in connection with the Medicare program, unless the context indicates otherwise—

Carrier means an entity that has a contract with CMS to determine and make Medicare payments for Part B benefits payable on a charge basis and to perform other related functions.

Critical access hospital (CAH) means a facility designated by HFCA as meeting the applicable requirements of section 1820 of the Act and of subpart F of part 485 of this chapter.

Departmental Appeals Board means: (1) Except as provided in paragraphs (2) and (3) of this definition, a Board established in the office of the Secretary, whose members act in panels to provide impartial review of disputed decisions made by operating components of the Department or by ALJs.

(2) For purposes of review of ALJ decisions under part 405, subparts G and H; part 417, subpart Q; part 422, subpart M; and part 478, subpart B of this chapter, the Medicare Appeals Council designated by the Board Chair.

(3) For purposes of part 426 of this chapter, a Member of the Board and, at the discretion of the Board Chair, any other Board staff appointed by the Board Chair to perform a review under that part.

Entitled means that an individual meets all the requirements for Medicare benefits.

Essential access community hospital (EACH) means a hospital designated by CMS as meeting the applicable requirements of section 1820 of the Act and of subpart G of part 412 of this chapter, as in effect on September 30, 1997.

GME stands for graduate medical education.

Hospital insurance benefits means payments on behalf of, and in rare circumstances directly to, an entitled individual for services that are covered under Part A of title XVIII of the Act.

Intermediary means an entity that has a contract with CMS to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis and to perform other related functions.

Local coverage determination (LCD) means a decision by a fiscal intermediary or a carrier under Medicare Part A or Part B, as applicable, whether to cover a particular service on an intermediary-wide or carrier-wide basis in accordance with section 1862(a)(1)(A) of the Act. An LCD may provide that a service is not reasonable and necessary for certain diagnoses and/or for certain diagnosis codes. An LCD does not include a determination of which procedure code, if any, is assigned to a service or a determination with respect to the amount of payment to be made for the service.

Medicare integrity program contractor means an entity that has a contract with CMS under section 1893 of the Act to perform exclusively one or more of the program integrity activities specified in that section.

Medicare Part A means the hospital insurance program authorized under Part A of title XVIII of the Act.

Medicare Part B means the supplementary medical insurance program authorized under Part B of title XVIII of the Act.

Medicare Part C means the choice of Medicare benefits through Medicare Advantage plans authorized under Part C of the title XVIII of the Act.

Medicare Part D means the voluntary prescription drug benefit program authorized under Part D of title XVIII of the Act.

National coverage determination (NCD) means a decision that CMS makes regarding whether to cover a particular service nationally under title XVIII of the Act. An NCD does not include a determination of what code, if any, is assigned to a service or a determination with respect to the amount of payment to be made for the service.

Nonparticipating supplier means a supplier that does not have an agreement

with CMS to participate in Part B of Medicare in effect on the date of the service.

Participating supplier means a supplier that has an agreement with CMS to participate in Part B of Medicare in effect on the date of the service.

Payment on an assignment-related basis means payment for Part B services—

(1) To a physician or other supplier that accepts assignment from the beneficiary, in accordance with § 424.55 or § 424.56 of this chapter;

(2) To a physician or other supplier after the beneficiary's death, in accordance with § 424.64(c)(1) of this chapter; or

(3) To an entity that pays the physician or other supplier under a health benefit plan, in accordance with § 424.66 of this chapter.

Provider means a hospital, a CAH, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

Railroad retirement benefits means monthly benefits payable to individuals under the Railroad Retirement Act of 1974 (45 U.S.C. beginning at section 231).

Services means medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital, CAH, or SNF facilities.

Supplementary medical insurance benefits means payment to or on behalf of an entitled individual for services covered under Part B of title XVIII of the Act.

Supplier means a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare.

[48 FR 12534, Mar. 25, 1983]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 400.202, see the List of CFR Sections Affected, which appears in the

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Finding Aids section of the printed volume and at *www.fdsys.gov*.

§ 400.203 Definitions specific to Medicaid.

As used in connection with the Medicaid program, unless the context indicates otherwise—

Applicant means an individual whose written application for Medicaid has been submitted to the agency determining Medicaid eligibility, but has not received final action. This includes an individual (who need not be alive at the time of application) whose application is submitted through a representative or a person acting responsibly for the individual.

Federal financial participation (FFP) means the Federal Government's share of a State's expenditures under the Medicaid program.

FMAP stands for the Federal medical assistance percentage, which is used to calculate the amount of Federal share of State expenditures for services.

Intellectual disability means the condition that was previously referred to as mental retardation.

Medicaid agency or agency means the single State agency administering or supervising the administration of a State Medicaid plan.

Nursing facility (NF), effective October 1, 1990, means an SNF or an ICF participating in the Medicaid program.

PCCM stands for primary care case manager.

PCP stands for primary care physician.

Provider means either of the following:

(1) For the fee-for-service program, any individual or entity furnishing Medicaid services under an agreement with the Medicaid agency.

(2) For the managed care program, any individual or entity that is engaged in the delivery of health care services and is legally authorized to do so by the State in which it delivers the services.

Services means the types of medical assistance specified in section 1905(a) of the Act and defined in subpart A of part 440 of this chapter.

State means the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Is-

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lands, Guam, American Samoa and the Northern Mariana Islands.

State plan or the plan means a comprehensive written commitment by a Medicaid agency, submitted under section 1902(a) of the Act, to administer or supervise the administration of a Medicaid program in accordance with Federal requirements.

[48 FR 12534, Mar. 25, 1983, as amended at 50 FR 33029, Aug. 16, 1985; 56 FR 8852, Mar. 1, 1991; 57 FR 29155, June 30, 1992; 67 FR 41094, June 14, 2002; 77 FR 29028, May 16, 2012]

Subpart C [Reserved]

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

Subpart A [Reserved]

Subpart B—Confidentiality and Disclosure

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AUTHORITY: Secs. 1102, 1871, and 1874(e) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395w-5) and sec. 105, Pub. L. 114-10, 129 Stat. 87.

Subpart A [Reserved]**Subpart B—Confidentiality and Disclosure**

SOURCE: 46 FR 55696, Nov. 12, 1981, unless otherwise noted.

§ 401.101 Purpose and scope.

(a) The regulations in this subpart:

(1) Implement section 1106(a) of the Social Security Act as it applies to the Centers for Medicare & Medicaid Services (CMS). The rules apply to information obtained by officers or employees of CMS in the course of administering title XVIII of the Social Security Act (Medicare), information obtained by Medicare intermediaries or carriers in the course of carrying out agreements under sections 1816 and 1842 of the Social Security Act, and any other information subject to section 1106(a) of the Social Security Act;

(2) Relate to the availability to the public, under 5 U.S.C. 552, of records of CMS and its components. They set out what records are available and how they may be obtained; and

(3) Supplement the regulations of the Department of Health and Human Services relating to availability of information under 5 U.S.C. 552, codified in 45 CFR part 5, and do not replace or restrict them.

(b) Except as authorized by the rules in this subpart, no information described in paragraph (a)(1) of this section shall be disclosed. The procedural rules in this subpart (§§ 401.106 through 401.152) shall be applied to requests for information which is subject to the rules for disclosure in this subpart.

(c) Requests for information which may not be disclosed according to the provisions of this subpart shall be denied under authority of section 1106(a) of the Social Security Act and this subpart, and furthermore, such requests which have been made pursuant to the Freedom of Information Act shall be denied under authority of an appropriate Freedom of Information Act exemption, 5 U.S.C. 552(b).

§ 401.102 Definitions.

For purposes of this subpart:

Act means the Social Security Act.

Freedom of Information Act rules means the substantive mandatory disclosure provisions of the Freedom of Information Act, 5 U.S.C. 552 (including the exemptions from mandatory disclosure, 5 U.S.C. 552(b), as implemented by the Department's public information regulation, 45 CFR part 5, subpart F

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and by §§ 401.106 to 401.152 of this subpart.

Person means a person as defined in the Administrative Procedure Act, 5 U.S.C. 551(2). This includes State or local agencies, but does not include Federal agencies or State or Federal courts.

Record has the same meaning as that provided in 45 CFR 5.5.

Subject individual means an individual whose record is maintained by the Department in a system of records, as the terms “individual,” “record,” and “system of records” are defined in the Privacy Act of 1974, 5 U.S.C. 552a(a).

§ 401.105 Rules for disclosure.

(a) *General rule.* The Freedom of Information Act rules shall be applied to every proposed disclosure of information. If, considering the circumstances of the disclosure, the information would be made available in accordance with the Freedom of Information Act rules, then the information may be disclosed regardless of whether the requester or beneficiary of the information has a statutory right to request the information under the Freedom of Information Act, 5 U.S.C. 552, or whether a request has been made.

(b) *Application of the general rule.* Pursuant to the general rule in paragraph (a) of this section,

(1) Information shall be disclosed—

(i) To a subject individual when required by the access provision of the Privacy Act, 5 U.S.C. 552a(d), as implemented by the Department Privacy Act regulation, 45 CFR part 5b; and

(ii) To a person upon request when required by the Freedom of Information Act, 5 U.S.C. 552;

(2) Unless prohibited by any other statute (e.g., the Privacy Act of 1974, 5 U.S.C. 552a(b), the Tax Reform Act of 1976, 26 U.S.C. 6103, or section 1106(d) and (e) of the Social Security Act), information may be disclosed to any requester or beneficiary of the information, including another Federal agency or a State or Federal court, when the information would not be exempt from mandatory disclosure under Freedom of Information Act rules or when the information nevertheless would be made available under the Department’s public information regulation’s cri-

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teria for disclosures which are in the public interest and consistent with obligations of confidentiality and administrative necessity, 45 CFR part 5, subpart F, as supplemented by §§ 401.106 to 401.152 of this subpart.

[42 FR 14704, Mar. 16, 1977. Redesignated at 45 FR 74913, 74914, Nov. 13, 1980, and correctly redesignated at 46 FR 24551, May 1, 1981, as amended at 46 FR 55697, Nov. 12, 1981]

§ 401.106 Publication.

(a) *Methods of publication.* Materials required to be published under the provisions of The Freedom of Information Act, 5 U.S.C. 552 (a)(1) and (2) are published in one of the following ways:

(1) By publication in the FEDERAL REGISTER of CMS regulations, and by their subsequent inclusion in the Code of Federal Regulations;

(2) By publication in the FEDERAL REGISTER of appropriate general notices;

(3) By other forms of publication, when incorporated by reference in the FEDERAL REGISTER with the approval of the Director of the Federal Register; and

(4) By publication of indexes of preceptual orders and opinions issued in the adjudication of claims, statements of policy and interpretations which have been adopted but have not been published in the FEDERAL REGISTER, and of administrative staff manuals and instructions to staff that affect a member of the public.

(b) *Availability for inspection.* Those materials which are published in the FEDERAL REGISTER pursuant to 5 U.S.C. 552(a)(1) shall, to the extent practicable and to further assist the public, be made available for inspection at the places specified in § 401.128.

[46 FR 55696, Nov. 12, 1981, as amended at 48 FR 22924, May 23, 1983]

§ 401.108 CMS rulings.

(a) After September 1981, a precedent final opinion or order or a statement of policy or interpretation that has not been published in the FEDERAL REGISTER as a part of a regulation or of a notice implementing regulations, but which has been adopted by CMS as having precedent, may be published in the FEDERAL REGISTER as a CMS Ruling

and will be made available in the publication entitled *CMS Rulings*.

(b) Precedent final opinions and orders and statements of policy and interpretation that were adopted by CMS before October, 1981, and that have not been published in the FEDERAL REGISTER are available in *CMS Rulings*.

(c) CMS Rulings are published under the authority of the Administrator, CMS. They are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

[48 FR 22924, May 23, 1983, as amended at 70 FR 11472, Mar. 8, 2005; 70 FR 37702, June 30, 2005]

§ 401.109 Precedential Final Decisions of the Secretary.

(a) The Chair of the Department of Health and Human Services Departmental Appeals Board (DAB Chair) may designate a final decision of the Secretary issued by the Medicare Appeals Council in accordance with part 405, subpart I; part 422, subpart M; part 423, subpart U; or part 478, subpart B, of this chapter as precedential. In determining which decisions should be designated as precedential, the DAB Chair may take into consideration decisions that address, resolve, or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest.

(b) Precedential decisions are made available to the public, with personally identifiable information of the beneficiary removed, and have precedential effect from the date they are made available to the public. Notice of precedential decisions is published in the FEDERAL REGISTER.

(c) Medicare Appeals Council decisions designated in accordance with paragraph (a) of this section have precedential effect and are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Se-

curity Administration adjudicate matters under the jurisdiction of CMS.

(d) Precedential effect, as used in this section, means that the Medicare Appeals Council's—

(1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and

(2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

[82 FR 5105, Jan. 17, 2017]

§ 401.110 Publications for sale.

The following publications containing information pertaining to the program, organization, functions, and procedures of CMS may be purchased from the Superintendent of Documents, Government Printing Office, Washington, DC 20402.

(a) Titles 20, 42, and 45 of the Code of Federal Regulations.

(b) FEDERAL REGISTER issues.

(c) Compilation of the Social Security Laws.

(d) CMS Rulings.

(e) Social Security Handbook. The information in the Handbook is not of precedent or interpretative force.

(f) Medicare/Medicaid Directory of Medical Facilities.

§ 401.112 Availability of administrative staff manuals.

All CMS administrative staff manuals and instructions to staff personnel which contain policies, procedures, or interpretations that affect the public are available for inspection and copying. A complete listing of such materials is published in CMS Rulings. These manuals are generally not printed in a sufficient quantity to permit sale or other general distribution to the public. Selected material is maintained at Social Security Administration district offices and field offices and may be inspected there. See §§ 401.130 and 401.132 for a listing of this material.

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§ 401.116 Availability of records upon request.

(a) *General.* In addition to the records made available pursuant to §§ 401.106, 401.108, 401.110 and 401.112, CMS will, upon request made in accordance with this subpart, make identified records available to any person, unless they are exempt from disclosure under the provisions of section 552(b) of title 5, United States Code (see § 401.126), or any other provision of law.

(b) *Misappropriation, alteration, or destruction of records.* No person may remove any record made available to him for inspection or copying under this part, from the place where it is made available. In addition, no person may steal, alter, mutilate, obliterate, or destroy in whole or in part, such a record. See sections 641 and 2071 of title 18 of the United States Code.

§ 401.118 Deletion of identifying details.

When CMS publishes or otherwise makes available an opinion or order, statement of policy, or other record which relates to a private party or parties, the name or names or other identifying details will be deleted.

§ 401.120 Creation of records.

Records will not be created by compiling selected items from the files, and records will not be created to provide the requester with such data as ratios, proportions, percentages, per capita, frequency distributions, trends, correlations, and comparisons. If such data have been compiled and are available in the form of a record, the record shall be made available as provided in this subpart.

§ 401.126 Information or records that are not available.

(a) *Specific exemptions from disclosure.* Pursuant to paragraph (b) of 5 U.S.C. 552, certain classes of records are exempt from disclosure. For some examples of the kinds of materials which are exempt, see subpart F of the public information regulation of the Department of Health and Human Services (45 CFR part 5) and the appendix to that regulation.

(b) *Materials exempt from disclosure by statute.* Pursuant to paragraph (b)(3) of

5 U.S.C. 552, as amended, which exempts from the requirement for disclosure matters that are exempted from disclosure by statute, provided that such statute requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or establishes particular criteria for withholding or refers to particular types of matter to be withheld:

(1) Reports described in sections 1106 (d) and (e) of the Social Security Act shall not be disclosed, except in accordance with the provisions of sections 1106 (d) and (e). Sections 1106 (d) and (e) provide for public inspection of certain official reports dealing with the operation of the health programs established by titles XVIII and XIX of the Social Security Act (Medicare and Medicaid), but require that program validation survey reports and other formal evaluations of providers of services shall not identify individual patients, individual health care practitioners, or other individuals. Section 1106(e) further requires that none of the reports shall be made public until the contractor or provider whose performance is being evaluated has had a reasonable opportunity to review that report and to offer comments. See § 401.133 (b) and (c);

(2)(i) Except as specified in paragraph (b)(2)(ii) of this section, CMS may not disclose any accreditation survey or any information directly related to the survey (including corrective action plans) made by and released to it by the Joint Commission on Accreditation of Healthcare Organizations, the American Osteopathic Association or any other national accreditation organization that meets the requirements of § 488.5 or § 493.506 of this chapter. Materials that are confidential include accreditation letters and accompanying recommendations and comments prepared by an accreditation organization concerning the entities it surveys.

(ii) *Exceptions.* (A) CMS may release the accreditation survey of any home health agency; and

(B) CMS may release the accreditation survey and other information directly related to the survey (including corrective action plans) to the extent the survey and information relate to an enforcement action (for example,

denial of payment for new admissions, civil money penalties, temporary management and termination) taken by CMS; and

(3) Tax returns and return information defined in section 6103 of the Internal Revenue Code, as amended by the Tax Reform Act of 1976, shall not be disclosed except as authorized by the Internal Revenue Code.

(c) *Effect of exemption.* Neither 5 U.S.C. 552 nor this regulation directs the withholding of any record or information, except to the extent of the prohibitions in paragraph (b) of this section. Except for material required to be withheld under the statutory provisions incorporated in paragraph (b) of this section or under another statute which meets the standards in 5 U.S.C. 552(b)(3), materials exempt from mandatory disclosure will nevertheless be made available when this can be done consistently with obligations of confidentiality and administrative necessity. The disclosure of materials or records under these circumstances in response to a specific request, however, is of no precedent force with respect to any other request.

[46 FR 55696, Nov. 12, 1981, as amended at 58 FR 61837, Nov. 23, 1993; 80 FR 29834, May 22, 2015]

§ 401.128 Where requests for records may be made.

(a) *General.* Any request for any record may be made to—

(1) Any CMS component;

(2) Director, Office of Public Affairs, CMS 313-H, Hubert H. Humphrey Building, 200 Independence Avenue, Washington, DC 20201; or

(3) Director of Public Affairs in any Regional Office of the Department of Health and Human Services.

The locations and service areas of these offices are as follows:

Region I—John F. Kennedy Federal Building, Boston, MA 02203. Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont.

Region II—26 Federal Plaza, New York, NY 10007. New York, New Jersey, Puerto Rico, Virgin Islands.

Region III—Gateway Building, 3535 Market Street, Philadelphia, PA 19101. Delaware, Maryland, Pennsylvania, Virginia, West Virginia, District of Columbia.

Region IV—101 Marietta Street, Atlanta, GA 30323. Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee.

Region V—300 South Wacker Drive, Chicago, IL 60606. Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin.

Region VI—1200 Main Tower Building, Dallas, TX 75202. Arkansas, Louisiana, New Mexico, Oklahoma, Texas.

Region VII—601 East 12th Street, Kansas City, MO 64106. Iowa, Kansas, Missouri, Nebraska.

Region VIII—Federal Office Building, 19th and Stout Streets, Denver, CO 80294. Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming.

Region IX—Federal Office Building, 50 United Nations Plaza, San Francisco, CA 94102. Arizona, California, Hawaii, Nevada, Guam, Trust Territory of Pacific Islands, American Samoa.

Region X—Arcade Plaza Building, 1321 Second Avenue, Seattle, WA 98101. Alaska, Idaho, Oregon, Washington.

(b) *Records pertaining to individuals.* CMS maintains some records pertaining to individuals. Disclosure of such records is generally prohibited by section 1106 of the Social Security Act (42 U.S.C. 1306), except as prescribed in § 401.105 (See also § 401.126(b)). Requests for records pertaining to individuals may be addressed to:

Director, Office of Research, Demonstrations and Statistics, CMS, Baltimore, Maryland 21235, when information is sought from the record of a person who has participated in a research survey conducted by or for CMS, Office of Research, Demonstrations and Statistics; or whose records have been included by statistical sampling techniques in research and statistical studies authorized by the Social Security Act in the field of health care financing.

(c) *Requests for materials listed in § 401.130 or § 401.132 or indexed in the CMS Rulings.* A request to inspect and copy materials listed in § 401.130 or § 401.132 or indexed in CMS Rulings may be made to any district or branch office of the Social Security Administration. If the specific material requested is not available in the office receiving the request, the material will be obtained and made available promptly.

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§ 401.130 Materials available at social security district offices and branch offices.

(a) *Materials available for inspection.* The following are available or will be made available for inspection at the social security district offices and branch offices:

(1) Compilation of the Social Security Laws.

(2) The Public Information Regulation of the Department of Health and Human Services (45 CFR part 5).

(3) Medicare Program regulations issued by the Centers for Medicare & Medicaid Services. 42 CFR chapter IV .

(4) CMS Rulings.

(5) Social Security Handbook.

(b) *Materials available for inspection and copying.* The following materials are available or will be made available for inspection and copying at the social security district offices and branch offices:

(1) Claims Manual of the Social Security Administration.

(2) Department Staff Manual on Organization, Department of Health and Human Services, Part F, CMS.

(3) Parts 2 and 3 of the Part A

Intermediary Manual (Provider Services under Medicare CMS Pub. 13-2 and 13-3).

(4) Parts 2 and 3 of the Part B Intermediary Manual (Physician and Supplier Services).

(5) Intermediary Letters Related to Parts 2 and 3 of the Part A and Part B Intermediary Manuals.

(6) State Buy-In Handbook (State Enrollment of Eligible Individuals under the Supplementary Medical Insurance Program) and Letters.

(7) Group Practice Prepayment Plan Manual (HIM-8) and Letters.

(8) State Operations Manual (HIM-7).

(9) CMS Letters to State Agencies on Medicare.

(10) Skilled Nursing Facility Manual (CMS Pub. 12).

(11) Hearing Officers Handbook (Supplementary Medical Insurance Program—HIM-21).

(12) Hospital Manual (HIM-10).

(13) Home Health Agency Manual (HIM-11).

(14) Outpatient Physical Therapy Provider Manual (HIM-9).

(15) Provider Reimbursement Manual (HIM-15).

(16) Audit Program Manuals for Hospital (HIM-16), Home Health Agency (HIM-17), and Extended Care Facilities (HIM-18).

(17) Statements of deficiencies based upon survey reports of health care institutions or facilities prepared after January 31, 1973, by a State agency, and such reports (including pertinent written statements furnished by such institution or facility on such statements of deficiencies), as set forth in § 401.133(a). Except as otherwise provided for at §§ 401.133 and 488.325 of this chapter for SNFs, such statements of deficiencies, reports, and pertinent written statements shall be available or made available only at the social security district office and regional office servicing the area in which the institution or facility is located, except that such statements of deficiencies and pertinent written statements shall also be available at the local public assistance offices servicing such area.

(18) Indexes to the materials listed in paragraph (a) of this section and in this paragraph (b) and an index to the Bureau of Hearings and Appeals Handbook.

[46 FR 55696, Nov. 12, 1981, as amended at 59 FR 56232, Nov. 10, 1994]

§ 401.132 Materials in field offices of the Office of Hearings and Appeals, SSA.

(a) *Materials available for inspection.* The following materials are available for inspection in the field offices of the Office of Hearings and Appeals, SSA.

(1) Title 45 of the Code of Federal Regulations (including the public information regulation of the Department of Health and Human Services).

(2) Regulations of the Social Security Administration and CMS.

(3) Title 5, United States Code.

(4) Compilation of the Social Security Laws.

(5) CMS Rulings.

(6) Social Security Handbook.

(b) *Handbook available for inspection and copying.* The Office of Hearings and Appeals Handbook is available for inspection and copying in the field offices of the Office of Hearings and Appeals.

§ 401.133 Availability of official reports on providers and suppliers of services, State agencies, intermediaries, and carriers under Medicare.

Except as otherwise provided for in § 488.325 of this chapter for SNFs, the following must be made available to the public under the conditions specified:

(a) *Statements of deficiencies and survey reports on providers of services prepared by State agencies.* (1) Statements of deficiencies based upon official survey reports prepared after January 31, 1973, by a State agency pursuant to its agreement entered into under section 1864 of the Social Security Act and furnished to CMS, which relate to a State agency's findings on the compliance of a health care institution or facility with the applicable provisions in section 1861 of the Act and with the regulations, promulgated pursuant to those provisions, dealing with health and safety of patients in those institutions and facilities; and (2) State agency survey reports. The statement of deficiencies or report and any pertinent written statements furnished by the institution or facility on the statement of deficiencies shall be disclosed within 90 days following the completion of the survey by the State agency, but not to exceed 30 days following the receipt of the report by CMS. (See § 401.130(b)(17)) for places where statements of deficiencies, reports, and pertinent written statements will be available.)

(b) *CMS reports on providers of services.* Upon request in writing, official reports and other formal evaluations (including followup reviews), excluding references to internal tolerance rules and practices contained therein, internal working papers or other informal memoranda, prepared and completed after January 31, 1973, which relate to the performance of providers of services under Medicare: *Provided*, That no information identifying individual patients, physicians, or other practitioners, or other individuals shall be disclosed under this paragraph. Those reports and other evaluations shall be disclosed within 30 days following the final preparation thereof by CMS during which time the providers of services shall be afforded a reasonable opportunity to offer comments, and there

shall be disclosed with those reports and evaluations any pertinent written statements furnished CMS by those providers on those reports and evaluations.

(c) *Contractor performance review reports.* Upon request in writing, official contractor performance review reports and other formal evaluations (including followup reviews), excluding references to internal tolerance rules and practices contained therein, internal working papers or other informal memoranda, prepared and completed after January 31, 1973, which relate to the evaluation of the performance of (1) intermediaries and carriers under their agreements entered into pursuant to sections 1816 and 1842 of the Social Security Act and (2) State agencies under their agreements entered into pursuant to section 1864 of the Act (including comparative evaluations of the performance of those intermediaries, carriers, and State agencies). The latest Contract Performance Review Report pertaining to a particular intermediary or carrier, prepared prior to February 1, 1973, may also be disclosed to any person upon request in writing. Those reports and evaluations shall be disclosed within 30 days following their final preparation by CMS (or 30 days following the request therefor, in the case of the contract performance review report prepared prior to February 1, 1973), during which time those intermediaries, carriers, and State agencies, as the case may be, shall be afforded a reasonable opportunity to offer comments, and there shall be disclosed with those reports and evaluations any pertinent written statements furnished CMS by those intermediaries, carriers, on State agencies or those reports and evaluations.

(d) *Accreditation surveys.* Upon written request, CMS will release the accreditation survey and related information from an accreditation organization meeting the requirements of § 488.5 or § 493.506 of this chapter to the extent the survey and information relate to an enforcement action taken (for example, denial of payment for new admission, civil money penalties, temporary management and termination) by CMS;

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(e) Upon written request, CMS will release the accreditation survey of any home health agency.

[46 FR 55696, Nov. 12, 1981; 46 FR 59249, Dec. 4, 1981, as amended at 58 FR 61838, Nov. 23, 1993; 59 FR 56232, Nov. 10, 1994; 80 FR 29834, May 22, 2015]

§ 401.134 Release of Medicare information to State and Federal agencies.

(a) Except as provided in paragraph (b) of this section, the following information may be released to an officer or employee of an agency of the Federal or a State government lawfully charged with the administration of a program receiving grants-in-aid under title V and XIX of the Social Security Act for the purpose of administration of those titles, or to any officer or employee of the Department of Army, Department of Defense, solely for the administration of its Civilian Health and Medical Program of the Uniformed Services (CHAMPUS):

(1) Information, including the identification number, concerning charges made by physicians, other practitioners, or suppliers, and amounts paid under Medicare for services furnished to beneficiaries by such physicians, other practitioners, or suppliers, to enable the agency to determine the proper amount of benefits payable for medical services performed in accordance with those programs; or

(2) Information as to physicians or other practitioners that has been disclosed under § 401.105.

(3) Information relating to the qualifications and certification status of hospitals and other health care facilities obtained in the process of determining whether, and certifying as to whether, institutions or agencies meet or continue to meet the conditions of participation of providers of services or whether other entities meet or continue to meet the conditions for coverage of services they furnish.

(b) The release of such information shall not be authorized by a fiscal intermediary or carrier.

(c) The following information may be released to any officer or employee of an agency of the Federal or a State government lawfully charged with the duty of conducting an investigation or prosecution with respect to possible

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fraud or abuse against a program receiving grants-in-aid under Medicaid, but only for the purpose of conducting such an investigation or prosecution, or to any officer or employee of the Department of the Army, Department of Defense, solely for the administration of its Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), provided that the agency has filed an agreement with CMS that the information will be released only to the agency's enforcement branch and that the agency will preserve the confidentiality of the information received and will not disclose that information for other than program purposes:

(1) The name and address of any provider of medical services, organization, or other person being actively investigated for possible fraud in connection with Medicare, and the nature of such suspected fraud. An active investigation exists when there is significant evidence supporting an initial complaint but there is need for further investigation.

(2) The name and address of any provider of medical services, organization, or other person found, after consultation with an appropriate professional association or a program review team, to have provided unnecessary services, or of any physician or other individual found to have violated the assignment agreement on at least three occasions.

(3) The name and address of any provider of medical services, organization or other person released under paragraph (c)(1) or (2) of this section concerning which an active investigation is concluded with a finding that there is no fraud or other prosecutable offense.

§ 401.135 Release of Medicare information to the public.

The following shall be made available to the public under the conditions specified:

(a) Information as to amounts paid to providers and other organizations and facilities for services to beneficiaries under title XVIII of the Act: *Provided*, That no information identifying any particular beneficiaries shall be disclosed under this paragraph.

(b) The name of any provider of services or other person furnishing services to Medicare beneficiaries who—

(1) Has been found by a Federal court to have been guilty of submitting false claims in connection with Medicare; or

(2) Has been found by a carrier or intermediary, after consultation with a professional medical association functioning external to program administration or, if appropriate, the State medical authority, to have been engaged in a pattern of furnishing services to beneficiaries which are substantially in excess of their medical needs; except that the name of any provider or other person shall not be disclosed pursuant to a finding under this paragraph (b)(2) of this section, unless that provider or other person has first been afforded a reasonable opportunity to offer evidence on his behalf.

(c) Upon request in writing, cost reports submitted by providers of services pursuant to section 1815 of the Act to enable the Secretary to determine amounts due the providers.

§ 401.136 Requests for information or records.

(a) A request should reasonably identify the requested record by brief description. Requesters who have detailed information which would assist in identifying the records requested are urged to provide such information in order to expedite the handling of the request. Envelopes in which written requests are submitted should be clearly identified as Freedom of Information requests. The request should include the fee or request determination of the fee. When necessary, a written request will be promptly forwarded to the proper office, and the requester will be advised of the date of the receipt and identification and address of the proper office.

(b) Determinations of whether records will be released or withheld will be made within 10 working days from date of receipt of the request in the office listed in § 401.128 except where CMS extends this time and sends notice of such extension to the requester. Such extension may not exceed 10 additional working days and shall apply only where the following unusual circumstances exist:

(1) The need to search for and collect the requested records from field facilities or other establishments that are separate from the office processing the requests;

(2) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are requested in a single request; or

(3) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the request or among two or more components of CMS having a substantial interest in the subject matter of the request.

(c) If an extension is made, the requester will be notified in writing before the expiration of 10 working days from receipt of the request and will be given an explanation of why the extension was necessary and the date on which a determination will be made.

(d) Authority to extend the time limit with respect to any request for information or records is granted to the Director, Office of Public Affairs, CMS and to the Director of Public Affairs in any HHS Regional Office. Those officers and employees of CMS who are listed in § 401.144(a) as having authority to deny requests for information from records maintained on individuals are granted authority to extend the time limit for responding to requests for information from such records.

§ 401.140 Fees and charges.

(a) *Statement of policy.* It is CMS's policy to comply with certain requests for information services without charge. Except as otherwise determined pursuant to paragraph (c) of this section, fees will be charged for the following services with respect to all other requests for information from records which are reasonably identified by the requesters:

(1) Reproduction, duplication, or copying of records;

(2) Searches for records; and

(3) Certification or authentication of records.

(b) *Fee schedules.* The fee schedule is as follows:

(1) *Search for records.* Three dollars per hour: *Provided, however,* That no

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charge will be made for the first half hour.

(2) *Reproduction, duplication, or copying of records.* Ten cents per page where such reproduction can be made by commonly available photocopying machines. The cost of reproducing records which cannot be so photocopied will be determined on an individual basis at actual cost.

(3) *Certification or authentication of records.* Three dollars per certification or authentication.

(4) *Forwarding materials to destination.* Any special arrangements for forwarding which are requested shall be charged at actual cost; however, no charge will be made for postage.

(5) No charge will be made when the total amount does not exceed five dollars.

(c) *Waiver or reduction of fees.* Waiver or reduction of the fees in paragraph (b) of this section may be made upon a determination that such waiver or reduction is in the public interest because furnishing the information can be considered as primarily benefiting the general public. Such determination may be made by the appropriate officer or employee identified in § 401.144.

(d) *Sale of documents.* On occasion, a previously printed document may be available for sale to the public; the cost of supplying the document is one cent per page unless the document is available for sale from the Superintendent of Documents, in which case the price shall be that determined by the Superintendent.

§ 401.144 Denial of requests.

(a) *General authority.* Only the Director, Office of Public Affairs, CMS, and the Regional Directors of Public Affairs, HHS, are authorized to deny written requests to obtain, inspect or copy any CMS information or record.

(b) *Forms of denials.* (1) Oral requests may be dealt with orally, but the requester should be advised that the oral response is not an official determination and that an official determination may be obtained only by submitting the request in writing. Appropriate available assistance will be offered.

(2) *Written Requests—Denials of written requests* will be in writing and will contain the reasons for the denial

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including, as appropriate, a statement that a document requested is non-existent or not reasonably described or is subject to one or more clearly described exemption(s). Denials will also provide the requester with appropriate information on how to exercise the right of appeal.

§ 401.148 Administrative review.

(a) *Review by the Administrator.* A person whose request has been denied may initiate a review by filing a request for review with the Administrator of CMS, 700 East High Rise Building, 6401 Security Boulevard, Baltimore, Maryland 21235, within 30 days of receipt of the determination to deny or within 30 days of receipt of records which are in partial response to his request if a portion of a request is granted and a portion denied, whichever is later. Upon receipt of a timely request for review, the Administrator will review the decision in question and the findings upon which it was based. Upon the basis of the data considered in connection with the decision and whatever other evidence and written argument is submitted by the person requesting the review or which is otherwise obtained, the Administrator or his designee will affirm or revise in whole or in part the findings and decision in question. A decision to affirm the denial will be made only upon concurrence of the Assistant Secretary for Public Affairs, or his designee, after consultation with the General Counsel or his or her designee, and the appropriate program policy official. Written notice of the decision of the Administrator will be mailed to the person who requested the review. A written decision will be made within 20 working days from receipt of the request for review. Extension of the time limit may be granted under the circumstances listed in § 401.136(b) to the extent that the maximum 10 days limit on extensions has not been exhausted on the initial determination. The decision will include the basis for it and will advise the requester of his right to judicial review.

(b) *Failure of the Administrator to comply with the time limits.* Failure of the Administrator to comply with the time

limits set forth in § 401.136 and this section constitutes an exhaustion of the requester's administrative remedies.

§ 401.152 Court review.

Where the Administrator upon review affirms the denial of a request for records, in whole or in part, the requester may seek court review in the district court of the United States pursuant to 5 U.S.C. 552(a)(4)(B).

Subpart C [Reserved]

Subpart D—Reporting and Returning of Overpayments

SOURCE: 81 FR 7683, Feb. 12, 2016, unless otherwise noted.

§ 401.301 Basis and scope.

This subpart sets forth the policies and procedures for reporting and returning overpayments to the Medicare program for providers and suppliers of services under Parts A and B of title XVIII of the Act as required by section 1128J(d) of the Act.

§ 401.303 Definitions.

For purposes of this subpart—

Medicare contractor means a Part A/ Part B Medicare Administrative Contractor (A/B MAC) or a Durable Medical Equipment Medicare Administrative Contractor (DME MAC).

Overpayment means any funds that a person has received or retained under title XVIII of the Act to which the person, after applicable reconciliation, is not entitled under such title.

Person means a provider (as defined in § 400.202 of this chapter) or a supplier (as defined in § 400.202 of this chapter).

§ 401.305 Requirements for reporting and returning of overpayments.

(a) *General.* (1) A person that has received an overpayment must report and return the overpayment in the form and manner set forth in this section.

(2) A person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the

overpayment. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment.

(b) *Deadline for reporting and returning overpayments.* (1) A person who has received an overpayment must report and return the overpayment by the later of either of the following:

(i) The date which is 60 days after the date on which the overpayment was identified.

(ii) The date any corresponding cost report is due, if applicable.

(2) The deadline for returning overpayments will be suspended when the following occurs:

(i) OIG acknowledges receipt of a submission to the OIG Self-Disclosure Protocol and will remain suspended until such time as a settlement agreement is entered, the person withdraws from the OIG Self-Disclosure Protocol, or the person is removed from the OIG Self-Disclosure Protocol.

(ii) CMS acknowledges receipt of a submission to the CMS Voluntary Self-Referral Disclosure Protocol and will remain suspended until such time as a settlement agreement is entered, the person withdraws from the CMS Voluntary Self-Referral Disclosure Protocol, or the person is removed from the CMS Voluntary Self-Referral Disclosure Protocol.

(iii) A person requests an extended repayment schedule as defined in § 401.603 and will remain suspended until such time as CMS or one of its contractors rejects the extended repayment schedule request or the provider or supplier fails to comply with the terms of the extended repayment schedule.

(c) *Applicable reconciliation.* (1) The applicable reconciliation occurs when a cost report is filed; and

(2) In instances when the provider—

(i) Receives more recent CMS information on the SSI ratio, the provider is not required to return any overpayment resulting from the updated information until the final reconciliation of the provider's cost report occurs; or

(ii) Knows that an outlier reconciliation will be performed, the provider is

not required to estimate the change in reimbursement and return the estimated overpayment until the final reconciliation of that cost report.

(d) *Reporting.* (1) A person must use an applicable claims adjustment, credit balance, self-reported refund, or other reporting process set forth by the applicable Medicare contractor to report an overpayment, except as provided in paragraph (d)(2) of this section. If the person calculates the overpayment amount using a statistical sampling methodology, the person must describe the statistically valid sampling and extrapolation methodology in the report.

(2) A person satisfies the reporting obligations of this section by making a disclosure under the OIG’s Self-Disclosure Protocol or the CMS Voluntary Self-Referral Disclosure Protocol resulting in a settlement agreement using the process described in the respective protocol.

(e) *Enforcement.* Any overpayment retained by a person after the deadline for reporting and returning the overpayment specified in paragraph (b) of this section is an obligation for purposes of 31 U.S.C. 3729.

(f) *Lookback period.* An overpayment must be reported and returned in accordance with this section if a person identifies the overpayment, as defined in paragraph (a)(2) of this section, within 6 years of the date the overpayment was received.

Subpart E [Reserved]

Subpart F—Claims Collection and Compromise

SOURCE: 48 FR 39064, Aug. 29, 1983, unless otherwise noted.

§ 401.601 Basis and scope.

(a) *Basis.* This subpart implements the following statutory provisions:

(1) For CMS the Debt Collection Improvement Act of 1996 (Pub. L. 104–134) (DCIA), 110 Stat. 1321, 1358 (April 26, 1996) (codified at 31 U.S.C. 3711), and conforms to the regulations (31 CFR parts 900–904) issued jointly by the Department of the Treasury and the Department of Justice that generally prescribe claims collection standards and

procedures under the DCIA for the Federal government.

(2) Section 1893(f)(1) of the Act regarding the use of repayment plans.

(b) *Scope.* Except as provided in paragraphs (c) through (f) of this section, the regulations in this subpart describe CMS’s procedures and standards for the collection of claims in any amount, and the compromise of, or the suspension or termination of collection action on, all claims for money or property that do not exceed \$100,000 or such higher amount as the Attorney General may from time to time prescribe, exclusive of interest, arising under any functions delegated to CMS by the Secretary.

(c) *Amount of claim.* CMS refers all claims that exceed \$100,000 or such higher amount as the Attorney General may from time to time prescribe, exclusive of interest, to the Department of Justice or the General Accounting Office for the compromise of claims, or the suspension or termination of collection action.

(d) *Related regulations—(1) Department regulations.* DHHS regulations applicable to CMS that generally implement the FCCA for the Department are located at 45 CFR part 30. These regulations apply only to the extent CMS regulations do not address a situation.

(2) *CMS regulations.* The following regulations govern specific debt management situations encountered by CMS and supplement this subpart:

(i) Claims against Medicare beneficiaries for the recovery of overpayments are covered in 20 CFR 404.515.

(ii) Adjustments in Railroad Retirement or Social Security benefits to recover Medicare overpayments to individuals are covered in §§ 405.350–405.358 of this chapter.

(iii) Claims against providers, physicians, or other suppliers of services for overpayments under Medicare and for assessment of interest are covered in §§ 405.377 and 405.378 of this chapter, respectively.

(iv) Claims against beneficiaries for unpaid hospital insurance or supplementary medical insurance premiums under Medicare are covered in § 408.110 of this chapter.

(v) State repayment of Medicaid funds by installments is covered in § 430.48 of this chapter.

(e) *Collection and compromise under other statutes and at common law.* The regulations in this subpart do not—

(1) Preclude disposition by CMS of claims under statutes, other than the FCCA, that provide for the collection or compromise of a claim, or suspension or termination of collection action.

(2) Affect any rights that CMS may have under common law as a creditor.

(f) *Fraud.* The regulations in this subpart do not apply to claims in which there is an indication of fraud, the presentation of a false claim, or misrepresentation on the part of a debtor or any other party having an interest in the claim. CMS forwards these claims to the Department of Justice for disposition under 4 CFR 105.1.

(g) *Enforced collection.* CMS refers claims to the Department of Justice for enforced collection through litigation in those cases which cannot be compromised or on which collection action cannot be suspended or terminated in accordance with this subpart or the regulations issued jointly by the Attorney General and the Comptroller General.

[48 FR 39064, Aug. 29, 1983, as amended at 52 FR 48123, Dec. 18, 1987; 57 FR 56998, Dec. 2, 1992; 61 FR 49271, Sept. 19, 1996; 61 FR 63748, Dec. 2, 1996; 73 FR 36447, June 27, 2008]

§ 401.603 Definitions.

For purposes of this subpart—

Claim means any debt owed to CMS.

Debtor means any individual, partnership, corporation, estate, trust or other legal entity against which CMS has a claim.

Extended repayment schedule means installment payments to pay back a debt.

[48 FR 39064, Aug. 29, 1983, as amended at 73 FR 36447, June 27, 2008]

§ 401.605 Omissions not a defense.

The failure of CMS to comply with the regulations in this subpart, or with the related regulations listed in § 401.601(d), is not available as a defense to a debtor against whom CMS has a claim for money or property.

§ 401.607 Claims collection.

(a) *General policy.* CMS recovers amounts of claims due from debtors, including interest where appropriate, by—

(1) Direct collections in lump sums or in installments; or

(2) Offsets against monies owed to the debtor by the Federal government where possible.

(b) *Collection in lump sums.* Whenever possible, CMS attempts to collect claims in full in one lump sum. However, if CMS determines that a debtor is unable to pay the claim in one lump sum, CMS may instead enter into an agreement to accept regular installment payments.

(c) *Collection in installments.* Generally, CMS requires that all claims to be satisfied by installment payments must be liquidated in three years or less. If unusual circumstances exist, such as the possibility of debtor insolvency, an installment agreement that extends beyond three years may be approved.

(1) *Debtor request.* If a debtor desires to repay a claim in installments, the debtor must submit—

(i) A request to CMS; and

(ii) Any information required by CMS to make a decision regarding the request.

(2) *Extended repayment schedule.* (i) For purposes of this paragraph (c)(2), the following definitions apply:

Extreme hardship exists when a provider or supplier qualifies as being in “hardship” as defined in this paragraph and the provider’s or supplier’s request for an extended repayment schedule (ERS) is approved under paragraph (c)(3) of this section.

Hardship exists when the total amount of all outstanding overpayments (principal and interest and including overpayments reported in accordance with §§ 401.301 through 401.305) not included in an approved, existing repayment schedule is 10 percent or greater than the total Medicare payments made for the cost reporting period covered by the most recently submitted cost report for a provider filing a cost report, or for the previous calendar year for a supplier or non cost-report provider.

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(ii) CMS or its contractor reviews a provider's or supplier's request for an ERS. For a provider or a supplier not paid by Medicare during the previous year or paid only during a portion of that year, the contractor or CMS will use the last 12 months of Medicare payments. If less than a 12-month payment history exists, the number of months available is annualized to equal an approximate yearly Medicare payment level for the provider or supplier.

(iii) For a provider or supplier requesting an ERS, CMS or its contractor evaluates the request based on the definitions and information submitted under this paragraph (c)(2). For a provider or supplier whose situation does not meet the definitions in paragraph (c)(2)(i) of this section, CMS or its contractor evaluates the ERS request using the information in paragraph (c)(3) of this section in deciding to grant an ERS.

(iv) CMS or its contractor is prohibited from granting an ERS to a provider or supplier if there is reason to suspect the provider or supplier may file for bankruptcy, cease to do business, discontinue participation in the Medicare program, or there is an indication of fraud or abuse committed against the Medicare program.

(v) CMS or its contractor may grant a provider or a supplier an ERS of at least 6 months if repaying an overpayment within 30 days will constitute a "hardship" as defined in paragraph (c)(2)(i) of this section. If a provider or supplier is granted an ERS under this paragraph, missing one installment payment constitutes a default and the total balance of the overpayment will be recovered immediately.

(vi) CMS or its contractor may grant a provider or a supplier an ERS of 36 months and up to 60 months if repaying an overpayment will constitute an "extreme hardship" as defined in paragraph (c)(2)(i) of this section.

(3) *CMS decision.* CMS will determine the number, amount and frequency of installment payments based on the information submitted by the debtor and on other factors such as—

- (i) Total amount of the claim;
- (ii) Debtor's ability to pay; and
- (iii) Cost to CMS of administering an installment agreement.

(d) *Collection by offset.* (1) CMS may offset, where possible, the amount of a claim against the amount of pay, compensation, benefits or other monies that a debtor is receiving or is due from the Federal government.

(2) Under regulations at § 405.350–405.358 of this chapter, CMS may initiate adjustments in program payments to which an individual is entitled under title II of the Act (Federal Old Age, Survivors, and Disability Insurance Benefits) or under the Railroad Retirement Act of 1974 (45 U.S.C. 231) to recover Medicare overpayments.

[48 FR 39064, Aug. 29, 1983, as amended at 61 FR 49271, Sept. 19, 1996; 61 FR 63748, Dec. 2, 1996; 73 FR 36447, June 27, 2008; 81 FR 7684, Feb. 12, 2016]

§ 401.613 Compromise of claims.

(a) *Amount of compromise.* HFCA requires that the amount to be recovered through a compromise of a claim must—

(1) Bear a reasonable relation to the amount of the claim; and

(2) Be recoverable through enforced collection procedures.

(b) *General factors.* After considering the bases for a decision to compromise a claim under paragraph (c) of this section, CMS may further consider factors such as—

(1) The age and health of the debtor if the debtor is an individual;

(2) Present and potential income of the debtor; and

(3) Whether assets have been concealed or improperly transferred by the debtor.

(c) *Basis for compromise.* Bases on which CMS may compromise a claim include the following—

(1) *Inability to pay.* CMS may compromise a claim if it determines that the debtor, or the estate of a deceased debtor, does not have the present or prospective ability to pay the full amount of the claim within a reasonable time.

(2) *Litigative probabilities.* CMS may compromise a claim if it determines that it would be difficult to prevail in a case before a court of law as a result of the legal issues involved or inability of the parties to agree to the facts of

the case. The amount that CMS accepts in compromise under this provision will reflect—

(i) The likelihood that CMS would have prevailed on the legal question(s) involved;

(ii) Whether and to what extent CMS would have obtained a full or partial recovery of a judgment, depending on the availability of witnesses, or other evidentiary support for CMS's claim; and

(iii) The amount of court costs that would be assessed to CMS.

(3) *Cost of collecting the claim.* CMS may compromise a claim if it determines that the cost of collecting the claim does not justify the enforced collection of the full amount. In this case, CMS may adjust the amount it accepts as a compromise to allow an appropriate discount for the costs of collection it would have incurred but for the compromise.

(d) *Enforcement policy.* CMS may compromise statutory penalties, forfeitures, or debts established as an aid to enforcement or to compel compliance, if it determines that its enforcement policy, in terms of deterrence and securing compliance both present and future, is adequately served by acceptance of the compromise amount.

§ 401.615 Payment of compromise amount.

(a) *Time and manner of compromise.* Payment by the debtor of the amount that CMS has agreed to accept as a compromise in full settlement of a claim must be made within the time and in the manner prescribed by CMS. Accordingly, CMS will not settle a claim until the full payment of the compromise amount has been made.

(b) *Effect of failure to pay compromise amount.* Failure of the debtor to make payment, as provided by the compromise agreement, reinstates the full amount of the claim, less any amounts paid prior to the default.

(c) *Prohibition against grace periods.* CMS will not agree to inclusion of a provision in an installment agreement that would permit grace periods for payments that are late under the terms of the agreement.

§ 401.617 Suspension of collection action.

(a) *General conditions.* CMS may temporarily suspend collection action on a claim if the following general conditions are met—

(1) *Amount of future recovery.* CMS determines that future collection action may result in a recovery of an amount sufficient to justify periodic review and action on the claim by CMS during the period of suspension.

(2) *Statute of limitations.* CMS determines that—

(i) The applicable statute of limitations has been tolled, waived or has started running anew; or

(ii) Future collections may be made by CMS through offset despite an applicable statute of limitations.

(b) *Basis for suspension.* Bases on which CMS may suspend collection action on a particular claim include the following—

(1) A debtor cannot be located; or

(2) A debtor—

(i) Owns no substantial equity in property;

(ii) Is unable to make payment on CMS's claim or is unable to effect a compromise; and

(iii) Has future prospects that justify retention of the claim.

(c) *Locating debtors.* CMS will make every reasonable effort to locate missing debtors sufficiently in advance of the bar of an applicable statute of limitations to permit timely filing of a lawsuit to recover the amount of the claim.

(d) *Effect of suspension on liquidation of security.* CMS will liquidate security, obtained in partial recovery of a claim, despite a decision under this section to suspend collection action against the debtor for the remainder of the claim.

§ 401.621 Termination of collection action.

(a) *General factors.* After considering the bases for a decision to terminate collection action under paragraph (b) of this section, CMS may further consider factors such as—

(1) The age and health of the debtor if the debtor is an individual;

(2) Present and potential income of the debtor; and

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(3) Whether assets have been concealed or improperly transferred by the debtor.

(b) *Basis for termination of collection action.* Bases on which CMS may terminate collection action on a claim include the following—

(1) *Inability to collect a substantial amount of the claim.* CMS may terminate collection action if it determines that it is unable to collect, or to enforce collection, of a significant amount of the claim. In making this determination, CMS will consider factors such as—

- (i) Judicial remedies available;
- (ii) The debtor's future financial prospects; and
- (iii) Exemptions available to the debtor under State or Federal law.

(2) *Inability to locate debtor.* In cases involving missing debtors, CMS may terminate collection action if—

- (i) There is no security remaining to be liquidated;
- (ii) The applicable statute of limitations has run; or
- (iii) The prospects of collecting by offset, whether or not an applicable statute of limitations has run, are considered by CMS to be too remote to justify retention of the claim.

(3) *Cost of collection exceeds recovery.* CMS may terminate collection action if it determines that the cost of further collection action will exceed the amount recoverable.

(4) *Legal insufficiency.* CMS may terminate collection action if it determines that the claim is legally without merit.

(5) *Evidence unavailable.* CMS may terminate collection action if—

- (i) Efforts to obtain voluntary payment are unsuccessful; and
- (ii) Evidence or witnesses necessary to prove the claim are unavailable.

§ 401.623 Joint and several liability.

(a) *Collection action.* CMS will liquidate claims as quickly as possible. In cases of joint and several liability among two or more debtors, CMS will not allocate the burden of claims payment among the debtors. CMS will proceed with collection action against one debtor even if other liable debtors have not paid their proportionate shares.

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(b) *Compromise.* Compromise with one debtor does not release a claim against remaining debtors. Furthermore, CMS will not consider the amount of a compromise with one debtor to be a binding precedent concerning the amounts due from other debtors who are jointly and severally liable on the claim.

§ 401.625 Effect of CMS claims collection decisions on appeals.

Any action taken under this subpart regarding the compromise of a claim, or suspension or termination of collection action on a claim, is not an initial determination for purposes of CMS appeal procedures.

Subpart G—Availability of Medicare Data for Performance Measurement

SOURCE: 76 FR 76567, Dec. 7, 2011, unless otherwise noted.

§ 401.701 Purpose and scope.

The regulations in this subpart implement section 1874(e) of the Social Security Act as it applies to Medicare data made available to qualified entities for the evaluation of the performance of providers and suppliers.

§ 401.703 Definitions.

For purposes of this subpart:

(a) *Qualified entity* means either a single public or private entity, or a lead entity and its contractors, that meets the following requirements:

- (1) Is qualified, as determined by the Secretary, to use claims data to evaluate the performance of providers and suppliers on measures of quality, efficiency, effectiveness, and resource use.
- (2) Agrees to meet the requirements described in this subpart at §§ 401.705 through 401.721.

(b) *Provider of services (referred to as a provider)* has the same meaning as the term “provider” in § 400.202 of this chapter.

(c) *Supplier* has the same meaning as the term “supplier” at § 400.202 of this chapter.

(d) *Claim* means an itemized billing statement from a provider or supplier that, except in the context of Part D prescription drug event data, requests

payment for a list of services and supplies that were furnished to a Medicare beneficiary in the Medicare fee-for-service context, or to a participant in other insurance or entitlement program contexts. In the Medicare program, claims files are available for each institutional (inpatient, outpatient, skilled nursing facility, hospice, or home health agency) and non-institutional (physician and durable medical equipment providers and suppliers) claim type as well as Medicare Part D Prescription Drug Event (PDE) data.

(e) *Standardized data extract* is a subset of Medicare claims data that the Secretary would make available to qualified entities under this subpart.

(f) *Beneficiary identifiable data* is any data that contains the beneficiary's name, Medicare Health Insurance Claim Number (HICN), or any other direct identifying factors, including, but not limited to postal address or telephone number.

(g) *Encrypted data* is any data that does not contain the beneficiary's name or any other direct identifying factors, but does include a unique CMS-assigned beneficiary identifier that allows for the linking of claims without divulging any direct identifier of the beneficiary.

(h) *Claims data from other sources* means provider- or supplier-identifiable claims data that an applicant or qualified entity has full data usage right to due to its own operations or disclosures from providers, suppliers, private payers, multi-payer databases, or other sources.

(i) *Clinical data* is registry data, chart-abstracted data, laboratory results, electronic health record information, or other information relating to the care or services furnished to patients that is not included in administrative claims data, but is available in electronic form.

(j) *Authorized user* is a third party and its contractors (including, where applicable, business associates as that term is defined at 45 CFR 160.103) that need analyses or data covered by this section to carry out work on behalf of that third party (meaning not the qualified entity or the qualified entity's contractors) to whom/which the

qualified entity provides or sells data as permitted under this subpart. Authorized user third parties are limited to the following entities:

- (1) A provider.
- (2) A supplier.
- (3) A medical society.
- (4) A hospital association.
- (5) An employer.
- (6) A health insurance issuer.
- (7) A healthcare provider and/or supplier association.
- (8) A state entity.
- (9) A federal agency.

(k) *Employer* has the same meaning as the term "employer" as defined in section 3(5) of the Employee Retirement Insurance Security Act of 1974.

(l) *Health insurance issuer* has the same meaning as the term "health insurance issuer" as defined in section 2791 of the Public Health Service Act.

(m) *Medical society* means a nonprofit organization or association that provides unified representation and advocacy for physicians at the national or state level and whose membership is comprised of a majority of physicians.

(n) *Hospital association* means a nonprofit organization or association that provides unified representation and advocacy for hospitals or health systems at a national, state, or local level and whose membership is comprised of a majority of hospitals and health systems.

(o) *Healthcare Provider and/or Supplier Association* means a nonprofit organization or association that provides unified representation and advocacy for providers and suppliers at the national or state level and whose membership is comprised of a majority of suppliers or providers.

(p) *State Entity* means any office, department, division, bureau, board, commission, agency, institution, or committee within the executive branch of a state government.

(q) *Combined data* means, at a minimum, a set of CMS claims data provided under this subpart combined with claims data, or a subset of claims data from at least one of the other claims data sources described in § 401.707(d).

(r) *Patient* means an individual who has visited the provider or supplier for

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a face-to-face or telehealth appointment at least once in the past 24 months.

(s) *Marketing* means the same as the term “marketing” at 45 CFR 164.501 without the exception to the bar for “consent” based marketing.

(t) *Violation* means a failure to comply with a requirement of a CMS DUA (CMS data use agreement) or QE DUA (qualified entity data use agreement).

(u) *Required by law* means the same as the phrase “required by law” at 45 CFR 164.103.

[76 FR 76567, Dec. 7, 2011, as amended at 81 FR 44479, July 7, 2016]

§ 401.705 Eligibility criteria for qualified entities.

(a) *Eligibility criteria*: To be eligible to apply to receive data as a qualified entity under this subpart, an applicant generally must demonstrate expertise and sustained experience, defined as 3 or more years, in the following three areas, as applicable and appropriate to the proposed use:

(1) Organizational and governance criteria, including:

(i) Expertise in the areas of measurement that they propose to use in accurately calculating quality, and efficiency, effectiveness, or resource use measures from claims data, including the following:

(A) Identifying an appropriate method to attribute a particular patient’s services to specific providers and suppliers.

(B) Ensuring the use of approaches to ensure statistical validity such as a minimum number of observations or minimum denominator for each measure.

(C) Using methods for risk-adjustment to account for variations in both case-mix and severity among providers and suppliers.

(D) Identifying methods for handling outliers.

(E) Correcting measurement errors and assessing measure reliability.

(F) Identifying appropriate peer groups of providers and suppliers for meaningful comparisons.

(ii) A plan for a business model that is projected to cover the costs of performing the required functions, including the fee for the data.

(iii) Successfully combining claims data from different payers to calculate performance reports.

(iv) Designing, and continuously improving the format of performance reports on providers and suppliers.

(v) Preparing an understandable description of the measures used to evaluate the performance of providers and suppliers so that consumers, providers and suppliers, health plans, researchers, and other stakeholders can assess performance reports.

(vi) Implementing and maintaining a process for providers and suppliers identified in a report to review the report prior to publication and providing a timely response to provider and supplier inquiries regarding requests for data, error correction, and appeals.

(vii) Establishing, maintaining, and monitoring a rigorous data privacy and security program, including disclosing to CMS any inappropriate disclosures of beneficiary identifiable information, violations of applicable federal and State privacy and security laws and regulations for the preceding 10-year period (or, if the applicant has not been in existence for 10 years, the length of time the applicant has been an organization), and any corrective actions taken to address the issues.

(viii) Accurately preparing performance reports on providers and suppliers and making performance report information available to the public in aggregate form, that is, at the provider or supplier level.

(2) Expertise in combining Medicare claims data with claims data from other sources, including demonstrating to the Secretary’s satisfaction that the claims data from other sources that it intends to combine with the Medicare data received under this subpart address the methodological concerns regarding sample size and reliability that have been expressed by stakeholders regarding the calculation of performance measures from a single payer source.

(3) Expertise in establishing, documenting and implementing rigorous data privacy and security policies including enforcement mechanisms.

(b) *Source of expertise and experience*: An applicant may demonstrate expertise and experience in any or all of the

areas described in paragraph (a) of this section through one of the following:

(1) Activities it has conducted directly through its own staff.

(2) Contracts with other entities if the applicant is the lead entity and includes documentation in its application of the contractual arrangements that exist between it and any other entity whose expertise and experience is relied upon in submitting the application.

§ 401.707 Operating and governance requirements for qualified entities.

A qualified entity must meet the following operating and governance requirements:

(a) Submit to CMS a list of all measures it intends to calculate and report, the geographic areas it intends to serve, and the methods of creating and disseminating reports. This list must include the following information, as applicable and appropriate to the proposed use:

(1) Name of the measure, and whether it is a standard or alternative measure.

(2) Name of the measure developer/owner.

(3) If it is an alternative measure, measure specifications, including numerator and denominator.

(4) The rationale for selecting each measure, including the relationship to existing measurement efforts and the relevancy to the population in the geographic area(s) the entity would serve, including the following:

(i) A specific description of the geographic area or areas it intends to serve.

(ii) A specific description of how each measure evaluates providers and suppliers on quality, efficiency, effectiveness, and/or resource use.

(5) A description of the methodologies it intends to use in creating reports with respect to all of the following topics:

(i) Attribution of beneficiaries to providers and/or suppliers.

(ii) Benchmarking performance data, including the following:

(A) Methods for creating peer groups.

(B) Justification of any minimum sample size determinations made.

(C) Methods for handling statistical outliers.

(iii) Risk adjustment, where appropriate.

(iv) Payment standardization, where appropriate.

(b) Submit to CMS a description of the process it would establish to allow providers and suppliers to view reports confidentially, request data, and ask for the correction of errors before the reports are made public.

(c) Submit to CMS a prototype report and a description of its plans for making the reports available to the public.

(d) Submit to CMS information about the claims data it possesses from other sources, as defined at § 401.703(h), and documentation of adequate rights to use the other claims data for the purposes of this subpart.

(e) If requesting a 5 percent national sample to calculate benchmarks for the specific measures it is using, submit to CMS a justification for needing the file to calculate benchmarks.

§ 401.709 The application process and requirements.

(a) *Application deadline.* CMS accepts qualified entity applications on a rolling basis after an application is made available on the CMS Web site. CMS reviews applications in the order in which they are received.

(b) *Selection criteria.* To be approved as a qualified entity under this subpart, the applicant must meet one of the following:

(1) *Standard approval process:* Meet the eligibility and operational and governance requirements, fulfill all of the application requirements to CMS' satisfaction, and agree to pay a fee equal to the cost of CMS making the data available. The applicant and each of its contractors that are anticipated to have access to the Medicare data must also execute a Data Use Agreement with CMS, that among other things, reaffirms the statutory ban on the use of Medicare data provided to the qualified entity by CMS under this subpart for purposes other than those referenced in this subpart.

(2) *Conditional approval process:* Meet the eligibility and operational and governance requirements, and fulfill all of the application requirements to CMS' satisfaction, with the exception of possession of sufficient claims data from

other sources. Meeting these requirements will result in a conditional approval as a qualified entity. Entities gaining a conditional approval as a qualified entity must meet the eligibility requirements related to claims data from other sources the entity intends to combine with the Medicare data, agree to pay a fee equal to the cost of CMS making the data available, and execute a Data Use Agreement with CMS, that among other things, reaffirms the statutory ban on the use of Medicare data provided to the qualified entity by CMS under this subpart for purposes other than those referenced in this subpart before receiving any Medicare data. If the qualified entity is composed of lead entity with contractors, any contractors that are anticipated to have access to the Medicare data must also execute a Data Use Agreement with CMS.

(c) *Duration of approval.* CMS permits an entity to participate as a qualified entity for a period of 3 years from the date of notification of the application approval by CMS. The qualified entity must abide by all CMS regulations and instructions. If the qualified entity wishes to continue performing the tasks after the 3-year approval period, the entity may re-apply for qualified entity status following the procedures in paragraph (f) of this section.

(d) *Reporting period.* A qualified entity must produce reports on the performance of providers and suppliers at least annually, beginning in the calendar year after they are approved by CMS.

(e) *The distribution of data—(1) Initial data release.* Once CMS fully approves a qualified entity under this subpart, the qualified entity must pay a fee equal to the cost of CMS making data available. After the qualified entity pays the fee, CMS will release the applicable encrypted claims data, as well as a file that crosswalks the encrypted beneficiary ID to the beneficiary name and the Medicare HICN. The data will be the most recent data available, and will be limited to the geographic spread of the qualified entity's other claims data, as determined by CMS.

(2) *Subsequent data releases.* After the first quarter of participation, CMS will provide a qualified entity with the

most recent additional quarter of currently available data, as well as a table that crosswalks the encrypted beneficiary ID to the beneficiary's name and the Medicare HICN. Qualified entities are required to pay CMS a fee equal to the cost of making data available before CMS will release the most recent quarter of additional data to the qualified entity.

(f) *Re-application.* A qualified entity that is in good standing may re-apply for qualified entity status. A qualified entity is considered to be in good standing if it has had no violations of the requirements in this subpart or if the qualified entity is addressing any past deficiencies either on its own or through the implementation of a corrective action plan. To re-apply a qualified entity must submit to CMS documentation of any changes to what was included in its previously-approved application. A re-applicant must submit this documentation at least 6 months before the end of its 3-year approval period and will be able to continue to serve as a qualified entity until the re-application is either approved or denied by CMS. If the re-application is denied, CMS will terminate its relationship with the qualified entity and the qualified entity will be subject to the requirements for return or destruction of data at §401.721(b).

§401.711 Updates to plans submitted as part of the application process.

(a) If a qualified entity wishes to make changes to the following parts of its previously-approved application:

(1) Its list of proposed measures—the qualified entity must send all the information referenced in §401.707(a) for the new measures to CMS at least 30 days before its intended confidential release to providers and suppliers.

(2) Its proposed prototype report—the qualified entity must send the new prototype report to CMS at least 30 days before its intended confidential release to providers and suppliers.

(3) Its plans for sharing the reports with the public—the qualified entity must send the new plans to CMS at least 30 days before its intended confidential release to providers and suppliers.

(b) CMS will notify the qualified entity when the entity's proposed changes are approved or denied for use, generally within 30 days of the qualified entity submitting the changes to CMS. If a CMS decision on approval or disapproval for a change is not forthcoming within 30 days and CMS does not request an additional 30 days for review, the change or modification shall be deemed to be approved.

(c) If the amount of claims data from other sources available to a qualified entity decreases, the qualified entity must immediately inform CMS and submit documentation that the remaining claims data from other sources is sufficient to address the methodological concerns regarding sample size and reliability. Under no circumstances may a qualified entity use Medicare data to create a report, use a measure, or share a report after the amount of claims data from other sources available to a qualified entity decreases until CMS determines either that the remaining claims data is sufficient or that the qualified entity has collected adequate additional data to address any deficiencies.

(1) If the qualified entity cannot submit the documentation required in paragraph (c) of this section, or if CMS determines that the remaining claims data is not sufficient, CMS will afford the qualified entity up to 120 days to obtain additional claims to address any deficiencies. If the qualified entity does not have access to sufficient new data after that time, CMS will terminate its relationship with the qualified entity.

(2) If CMS determines that the remaining claims data is sufficient, the qualified entity may continue issuing reports, using measures, and sharing reports.

§ 401.713 Ensuring the privacy and security of data.

(a) *Data use agreement between CMS and a qualified entity.* A qualified entity must comply with the data requirements in its data use agreement with CMS (hereinafter the CMS DUA). Contractors (including, where applicable, business associates) of qualified entities that are anticipated to have access to the Medicare claims data or beneficiary identifiable data in the context

of this program are also required to execute and comply with the CMS DUA. The CMS DUA will require the qualified entity to maintain privacy and security protocols throughout the duration of the agreement with CMS, and will ban the use or disclosure of Medicare data or any derivative data for purposes other than those set out in this subpart. The CMS DUA will also prohibit the use of unsecured telecommunications to transmit such data, and will specify the circumstances under which such data must be stored and may be transmitted.

(b) A qualified entity must inform each beneficiary whose beneficiary identifiable data has been (or is reasonably believed to have been) inappropriately accessed, acquired, or disclosed in accordance with the DUA.

(c) Contractor(s) must report to the qualified entity whenever there is an incident where beneficiary identifiable data has been (or is reasonably believed to have been) inappropriately accessed, acquired, or disclosed.

(d) *Data use agreement between a qualified entity and an authorized user.* In addition to meeting the other requirements of this subpart, and as a precondition of selling or disclosing any combined data or any Medicare claims data (or any beneficiary-identifiable derivative data of either kind) and as a precondition of selling or disclosing non-public analyses that include individually identifiable beneficiary data, the qualified entity must enter a DUA (hereinafter the QE DUA) with the authorized user. Among other things laid out in this subpart, such QE DUA must contractually bind the authorized user (including any contractors or business associates described in the definition of authorized user) to the following:

(1)(i) The authorized user may be permitted to use such data and non-public analyses in a manner that a HIPAA Covered Entity could do under the following provisions:

(A) Activities falling under paragraph (1) of the definition of "health care operations" under 45 CFR 164.501: Quality improvement activities, including care coordination activities and efforts to track and manage medical costs; patient-safety activities; population-based activities such as

those aimed at improving patient safety, quality of care, or population health, including the development of new models of care, the development of means to expand coverage and improve access to healthcare, the development of means of reducing healthcare disparities, and the development or improvement of methods of payment or coverage policies.

(B) Activities falling under paragraph (2) of the definition of “health care operations” under 45 CFR 164.501: Reviewing the competence or qualifications of health care professionals, evaluating practitioner and provider performance, health plan performance, conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers, training of non-health care professionals, accreditation, certification, licensing, or credentialing activities.

(C) Activities that qualify as “fraud and abuse detection or compliance activities” under 45 CFR 164.506(c)(4)(ii).

(D) Activities that qualify as “treatment” under 45 CFR 164.501.

(ii) All other uses and disclosures of such data and/or such non-public analyses must be forbidden except to the extent a disclosure qualifies as a “required by law” disclosure as defined at 45 CFR 164.103.

(2) The authorized user is prohibited from using or disclosing the data or non-public analyses for marketing purposes as defined at § 401.703(s).

(3) The authorized user is required to ensure adequate privacy and security protection for such data and non-public analyses. At a minimum, regardless of whether the authorized user is a HIPAA covered entity, such protections of beneficiary identifiable data must be at least as protective as what is required of covered entities and their business associates regarding protected health information (PHI) under the HIPAA Privacy and Security Rules. In all cases, these requirements must be imposed for the life of such beneficiary identifiable data or non-public analyses and/or any derivative data, that is until all copies of such data or non-public analyses are returned or destroyed. Such duties must be written

in such a manner as to survive termination of the QE DUA, whether for cause or not.

(4) Except as provided for in paragraph (d)(5) of this section, the authorized user must be prohibited from re-disclosing or making public any such data or non-public analyses.

(5)(i) At the qualified entity’s discretion, it may permit an authorized user that is a provider as defined in § 401.703(b) or a supplier as defined in § 401.703(c), to re-disclose such data and non-public analyses as a covered entity will be permitted to disclose PHI under 45 CFR 164.506(c)(4)(i), under 45 CFR 164.506(c)(2), or under 45 CFR 164.502(e)(1).

(ii) All other uses and disclosures of such data and/or such non-public analyses is forbidden except to the extent a disclosure qualifies as a “required by law” disclosure.

(6) Authorized users who/that receive the beneficiary de-identified combined data or Medicare data as contemplated under § 401.718 are contractually prohibited from linking the beneficiary de-identified data to any other identifiable source of information, and must be contractually barred from attempting any other means of re-identifying any individual whose data is included in such data.

(7) The QE DUA must bind authorized user(s) to notifying the qualified entity of any violations of the QE DUA, and it must require the full cooperation of the authorized user in the qualified entity’s efforts to mitigate any harm that may result from such violations, or to comply with the breach provisions governing qualified entities under this subpart.

[76 FR 76567, Dec. 7, 2011, as amended at 81 FR 44479, July 7, 2016]

§ 401.715 Selection and use of performance measures.

(a) *Standard measures.* A standard measure is a measure that can be calculated in full or in part from claims data from other sources and the standardized extracts of Medicare Parts A and B claims, and Part D prescription drug event data and meets the following requirements:

(1) Meets one of the following criteria:

(i) Is endorsed by the entity with a contract under section 1890(a) of the Social Security Act.

(ii) Is time-limited endorsed by the entity with a contract under section 1890(a) of the Social Security Act until such time as the full endorsement status is determined.

(iii) Is developed under section 931 of the Public Health Service Act.

(iv) Can be calculated from standardized extracts of Medicare Parts A or B claims or Part D prescription drug event data, was adopted through notice-and-comment rulemaking, and is currently being used in CMS programs that include quality measurement.

(v) Is endorsed by a CMS-approved consensus-based entity. CMS will approve organizations as consensus-based entities based on review of documentation of the consensus-based entity's measure approval process. To receive approval as a consensus-based entity, an organization must submit information to CMS documenting its processes for stakeholder consultation and measures approval; an organization will only receive approval as a consensus-based entity if all measure specifications are publically available. An organization will retain CMS acceptance as a consensus-based entity for 3 years after the approval date, at which time CMS will review new documentation of the consensus-based entity's measure approval process for a new 3-year approval.

(2) Is used in a manner that follows the measure specifications as written (or as adopted through notice-and-comment rulemaking), including all numerator and denominator inclusions and exclusions, measured time periods, and specified data sources.

(b) *Alternative measure.* (1) An alternative measure is a measure that is not a standard measure, but that can be calculated in full, or in part, from claims data from other sources and the standardized extracts of Medicare Parts A and B claims, and Part D prescription drug event data, and that meets one of the following criteria:

(i) *Rulemaking process:* Has been found by the Secretary, through a notice-and-comment-rulemaking process, to be more valid, reliable, responsive to consumer preferences, cost-effective, or

relevant to dimensions of quality and resource use not addressed by standard measures, and is used by a qualified entity in a manner that follows the measure specifications as adopted through notice-and-comment rulemaking, including all numerator and denominator inclusions and exclusions, measured time periods, and specified data sources.

(ii) *Stakeholder consultation approval process:* Has been found by the Secretary, using documentation submitted by a qualified entity that outlines its consultation and agreement with stakeholders in its community, to be more valid, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by standard measures, and is used by a qualified entity in a manner that follows the measure specifications as submitted, including all numerator and denominator inclusions and exclusions, measured time periods, and specified data sources. If a CMS decision on approval or disapproval of alternative measures submitted using the stakeholder consultation approval process is not forthcoming within 60 days of submission of the measure by the qualified entity, the measure will be deemed approved. However, CMS retains the right to disapprove a measure if, even after 60 days, we find it to not be "more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource" than a standard measure.

(2) An alternative measure approved under the process at paragraph (b)(1)(i) of this section may be used by any qualified entity. An alternative measure approved under the process at paragraph (b)(1)(ii) of this section may only be used by the qualified entity that submitted the measure for consideration by the Secretary. A qualified entity may use an alternative measure up until the point that an equivalent standard measure for the particular clinical area or condition becomes available at which point the qualified entity must switch to the standard measure within 6 months or submit additional scientific justification and receive approval, via either paragraphs (b)(1)(i) or (b)(1)(ii) of this section, from

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the Secretary to continue using the alternative measure.

(3) To submit an alternative measure for consideration under the notice-and-comment-rulemaking process, for use in the calendar year following the submission, an entity must submit the following information by May 31st:

(i) The name of the alternative measure.

(ii) The name of the developer or owner of the alternative measure.

(iii) Detailed specifications for the alternative measure.

(iv) Evidence that use of the alternative measure would be more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by standard measures.

(4) To submit an alternative measure for consideration under the documentation of stakeholder consultation approval process described in paragraph (b)(1)(ii) of this section, for use once the measure is approved by the Secretary, an entity must submit the following information to CMS:

(i) The name of the alternative measure.

(ii) The name of the developer or owner of the alternative measure.

(iii) Detailed specifications for the alternative measure.

(iv) A description of the process by which the qualified entity notified stakeholders in the geographic region it serves of its intent to seek approval of an alternative measure. Stakeholders must include a valid cross representation of providers, suppliers, payers, employers, and consumers.

(v) A list of stakeholders from whom feedback was solicited, including the stakeholders' names and roles in the community.

(vi) A description of the discussion about the proposed alternative measure, including a summary of all pertinent arguments supporting and opposing the measure.

(vii) Unless CMS has already approved the same measure for use by another qualified entity, no new scientific evidence on the measure is available, and the subsequent qualified entity wishes to rely upon the scientific evidence submitted by the previously approved applicant, an expla-

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nation backed by scientific evidence that demonstrates why the measure is more valid, reliable, responsive to consumer preferences, cost-effective, or relevant to dimensions of quality and resource use not addressed by a standard measure.

§ 401.716 Non-public analyses.

(a) *General.* So long as it meets the other requirements of this subpart, and subject to the limits in paragraphs (b) and (c) of this section, the qualified entity may use the combined data to create non-public analyses in addition to performance measures and provide or sell these non-public analyses to authorized users (including any contractors or business associates described in the definition of authorized user).

(b) *Limitations on a qualified entity.* In addition to meeting the other requirements of this subpart, a qualified entity must comply with the following limitations as a pre-condition of dissemination or selling non-public analyses to an authorized user:

(1) A qualified entity may only provide or sell a non-public analysis to a health insurance issuer as defined in § 401.703(1), after the health insurance issuer or a business associate of that health insurance issuer has provided the qualified entity with claims data that represents a majority of the health insurance issuer's covered lives, using one of the four methods of calculating covered lives established at 26 CFR 46.4375–1(c)(2), for the time period and geographic region covered by the issuer-requested non-public analyses. A qualified entity may not provide or sell a non-public analysis to a health insurance issuer if the issuer does not have any covered lives in the geographic region covered by the issuer-requested non-public analysis.

(2) Analyses that contain information that individually identifies one or more beneficiaries may only be disclosed to a provider or supplier (as defined at § 401.703(b) and (c)) when both of the following conditions are met:

(i) The analyses only contain identifiable information on beneficiaries with whom the provider or supplier have a patient relationship as defined at § 401.703(r).

(ii) A QE DUA as defined at § 401.713(d) is executed between the qualified entity and the provider or supplier prior to making any individually identifiable beneficiary information available to the provider or supplier.

(3) Except as specified under paragraph (b)(2) of this section, all analyses must be limited to beneficiary de-identified data. Regardless of the HIPAA covered entity or business associate status of the qualified entity and/or the authorized user, de-identification must be determined based on the standards for HIPAA covered entities found at 45 CFR 164.514(b).

(4) Analyses that contain information that individually identifies a provider or supplier (regardless of the level of the provider or supplier, that is, individual clinician, group of clinicians, or integrated delivery system) may not be disclosed unless one of the following three conditions apply:

(i) The analysis only individually identifies the provider or supplier that is being supplied the analysis.

(ii) Every provider or supplier individually identified in the analysis has been afforded the opportunity to appeal or correct errors using the process at § 401.717(f).

(iii) Every provider or supplier individually identified in the analysis has notified the qualified entity, in writing, that analyses can be disclosed to the authorized user without first going through the appeal and error correction process at § 401.717(f).

(c) *Non-public analyses agreement between a qualified entity and an authorized user for beneficiary de-identified non-public analyses disclosures.* In addition to the other requirements of this subpart, a qualified entity must enter a contractually binding non-public analyses agreement with the authorized user (including any contractors or business associates described in the definition of authorized user) as a precondition to providing or selling de-identified analyses. Such non-public analyses agreement must contain the following provisions:

(1) The authorized user may not use the analyses or derivative data for the following purposes:

(i) Marketing, as defined at § 401.703(s).

(ii) Harming or seeking to harm patients or other individuals both within and outside the healthcare system regardless of whether their data are included in the analyses.

(iii) Effectuating or seeking opportunities to effectuate fraud and/or abuse in the healthcare system.

(2) If the authorized user is an employer as defined in § 401.703(k), the authorized user may only use the analyses or derivative data for purposes of providing health insurance to employees, retirees, or dependents of employees or retirees of that employer.

(3)(i) At the qualified entity's discretion, it may permit an authorized user that is a provider as defined in § 401.703(b) or a supplier as defined in § 401.703(c), to re-disclose the de-identified analyses or derivative data, as a covered entity will be permitted under 45 CFR 164.506(c)(4)(i), or under 45 CFR 164.502(e)(1).

(ii) All other uses and disclosures of such data and/or such non-public analyses is forbidden except to the extent a disclosure qualifies as a "required by law" disclosure.

(4) If the authorized user is not a provider or supplier, the authorized user may not re-disclose or make public any non-public analyses or derivative data except as required by law.

(5) The authorized user may not link the de-identified analyses to any other identifiable source of information and may not in any other way attempt to identify any individual whose de-identified data is included in the analyses.

(6) The authorized user must notify the qualified entity of any DUA violations, and it must fully cooperate with the qualified entity's efforts to mitigate any harm that may result from such violations.

[81 FR 44480, July 7, 2016]

§ 401.717 Provider and supplier requests for error correction.

(a) A qualified entity must confidentially share measures, measurement methodologies, and measure results with providers and suppliers at least 60 calendar days before making reports public. The 60 calendar days begin on the date on which qualified entities

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send the confidential reports to providers and suppliers. A qualified entity must inform providers and suppliers of the date the reports will be made public at least 60 calendar days before making the reports public.

(b) Before making the reports public, a qualified entity must allow providers and suppliers the opportunity to make a request for the data, or to make a request for error correction, within 60 calendar days after sending the confidential reports to providers or suppliers.

(c) During the 60 calendar days between sending a confidential report on measure results and releasing the report to the public, the qualified entity must, at the request of a provider or supplier and with appropriate privacy and security protections, release the Medicare claims data and beneficiary names to the provider or supplier. Qualified entities may only provide the Medicare claims and/or beneficiary names relevant to the particular measure or measure result the provider or supplier is appealing.

(d) A qualified entity must inform providers and suppliers that reports will be made public, including information related to the status of any data or error correction requests, after the date specified to the provider or supplier when the report is sent for review and, if necessary, error correction requests (at least 60 calendar days after the report was originally sent to the providers and suppliers), regardless of the status of any requests for error correction.

(e) If a provider or supplier has a data or error correction request outstanding at the time the reports become public, the qualified entity must, if feasible, post publicly the name of the appealing provider or supplier and the category of the appeal request.

(f) A qualified entity must comply with the following requirements before disclosing non-public analyses, as defined at § 401.716, which contain information that individually identifies a provider or supplier:

(1) A qualified entity must confidentially notify a provider or supplier that non-public analyses that individually identify the provider or supplier are going to be released to an authorized

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user at least 65 calendar days before disclosing the analyses. This confidential notification must include a short summary of the analyses (including the measures calculated), the process for the provider or supplier to request the analyses, the authorized users receiving the analyses, and the date on which the qualified entity will release the analyses to the authorized user.

(2) A qualified entity must allow providers and suppliers the opportunity to opt-in to the review and correction process as defined in paragraphs (a) through (e) of this section, anytime during the 65 calendar days. If a provider or supplier chooses to opt-in to the review and correction process more than 5 days into the notification period, the time for the review and correction process is shortened from 60 days to the number of days between the provider or supplier opt-in date and the release date specified in the confidential notification.

[76 FR 76567, Dec. 7, 2011, as amended at 81 FR 44481, July 7, 2016]

§ 401.718 Dissemination of data.

(a) *General.* Subject to the other requirements in this subpart, the requirements in paragraphs (b) and (c) of this section and any other applicable laws or contractual agreements, a qualified entity may provide or sell combined data or provide Medicare data at no cost to authorized users defined at § 401.703(b), (c), (m), and (n).

(b) *Data*—(1) *De-identification.* Except as specified in paragraph (b)(2) of this section, any data provided or sold by a qualified entity to an authorized user must be limited to beneficiary de-identified data. De-identification must be determined based on the de-identification standards for HIPAA covered entities found at 45 CFR 164.514(b).

(2) *Exception.* If such disclosure will be consistent with all applicable laws, data that individually identifies a beneficiary may only be disclosed to a provider or supplier (as defined at § 401.703(b) and (c)) with whom the identifiable individuals in such data have a current patient relationship as defined at § 401.703(r).

(c) *Data use agreement between a qualified entity and an authorized user.* A

qualified entity must contractually require an authorized user to comply with the requirements in § 401.713(d) prior to providing or selling data to an authorized user under § 401.718.

[81 FR 44481, July 7, 2016]

§ 401.719 Monitoring and sanctioning of qualified entities.

(a) CMS will monitor and assess the performance of qualified entities and their contractors using the following methods:

- (1) Audits.
 - (2) Submission of documentation of data sources and quantities of data upon the request of CMS and/or site visits.
 - (3) Analysis of specific data reported to CMS by qualified entities through annual reports (as described in paragraph (b) of this section) and reports on inappropriate disclosures or uses of beneficiary identifiable data (as described in paragraph (c) of this section).
 - (4) Analysis of complaints from beneficiaries and/or providers or suppliers.
- (b) A qualified entity must provide annual reports to CMS containing information related to the following:
- (1) General program adherence, including the following information:
 - (i) The number of Medicare and private claims combined.
 - (ii) The percent of the overall market share the number of claims represent in the qualified entity's geographic area.
 - (iii) The number of measures calculated.
 - (iv) The number of providers and suppliers profiled by type of provider and supplier.
 - (v) A measure of public use of the reports.
 - (2) The provider and supplier data sharing, error correction, and appeals process, including the following information:
 - (i) The number of providers and suppliers requesting claims data.
 - (ii) The number of requests for claims data fulfilled.
 - (iii) The number of error corrections.
 - (iv) The type(s) of problem(s) leading to the request for error correction.

(v) The amount of time to acknowledge the request for data or error correction.

(vi) The amount of time to respond to the request for error correction.

(vii) The number of requests for error correction resolved.

(3) Non-public analyses provided or sold to authorized users under this subpart, including the following information:

(i) A summary of the analyses provided or sold, including—

(A) The number of analyses.

(B) The number of purchasers of such analyses.

(C) The types of authorized users that purchased analyses.

(D) The total amount of fees received for such analyses.

(E) QE DUA or non-public analyses agreement violations.

(ii) A description of the topics and purposes of such analyses.

(iii) The number of analyses disclosed with unresolved requests for error correction.

(4) Data provided or sold to authorized users under this subpart, including the following information:

(i) The entities who received data.

(ii) The basis under which each entity received such data.

(iii) The total amount of fees received for providing, selling, or sharing the data.

(iv) QE DUA violations.

(c) A qualified entity must inform CMS of inappropriate disclosures or uses of beneficiary identifiable data under the DUA.

(d) CMS may take the following actions against a qualified entity if CMS determines that the qualified entity violated any of the requirements of this subpart, regardless of how CMS learns of a violation:

(1) Provide a warning notice to the qualified entity of the specific concern, which indicates that future deficiencies could lead to termination.

(2) Request a corrective action plan (CAP) from the qualified entity.

(3) Place the qualified entity on a special monitoring plan.

(4) Terminate the qualified entity.

(5) In the case of a violation, as defined at § 401.703(t), of the CMS DUA or

the QE DUA, CMS will impose an assessment on a qualified entity in accordance with the following:

(i) *Amount of assessment.* CMS will calculate the amount of the assessment of up to \$100 per individual entitled to, or enrolled for, benefits under part A of title XVIII of the Social Security Act or enrolled for benefits under Part B of such title whose data was implicated in the violation based on the following:

(A) *Basic factors.* In determining the amount per impacted individual, CMS takes into account the following:

(1) The nature and the extent of the violation.

(2) The nature and the extent of the harm or potential harm resulting from the violation.

(3) The degree of culpability and the history of prior violations.

(B) *Criteria to be considered.* In establishing the basic factors, CMS considers the following circumstances:

(1) *Aggravating circumstances.* Aggravating circumstances include the following:

(i) There were several types of violations occurring over a lengthy period of time.

(ii) There were many of these violations or the nature and circumstances indicate a pattern of violations.

(iii) The nature of the violation had the potential or actually resulted in harm to beneficiaries.

(2) *Mitigating circumstances.* Mitigating circumstances include the following:

(i) All of the violations subject to the imposition of an assessment were few in number, of the same type, and occurring within a short period of time.

(ii) The violation was the result of an unintentional and unrecognized error and the qualified entity took corrective steps immediately after discovering the error.

(C) *Effects of aggravating or mitigating circumstances.* In determining the amount of the assessment to be imposed under paragraph (d)(5)(i)(A) of this section:

(1) If there are substantial or several mitigating circumstance, the aggregate amount of the assessment is set at an amount sufficiently below the maximum permitted by paragraph

(d)(5)(i)(A) of this section to reflect the mitigating circumstances.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the assessment is set at an amount at or sufficiently close to the maximum permitted by paragraph (d)(5)(i)(A) of this section to reflect the aggravating circumstances.

(D) The standards set for the qualified entity in this paragraph are binding, except to the extent that—

(1) 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.

(2) Nothing in this section limits the authority of CMS to settle any issue or case as provided by part 1005 of this title or to compromise any assessment as provided by paragraph (d)(5)(ii)(E) of this section.

(i) *Notice of determination.* CMS must propose an assessment in accordance with this paragraph (d)(5), by notifying the qualified entity by certified mail, return receipt requested. Such notice must include the following information:

(A) The assessment amount.

(B) The statutory and regulatory bases for the assessment.

(C) A description of the violations upon which the assessment was proposed.

(D) Any mitigating or aggravating circumstances that CMS considered when it calculated the amount of the proposed assessment.

(E) Information concerning response to the notice, including:

(1) A specific statement of the respondent's right to a hearing in accordance with procedures established at Section 1128A of the Act and implemented in 42 CFR part 1005.

(2) A statement that failure to respond within 60 days renders the proposed determination final and permits the imposition of the proposed assessment.

(3) A statement that the debt may be collected through an administrative offset.

(4) In the case of a respondent that has an agreement under section 1866 of the Act, notice that imposition of an exclusion may result in termination of the provider's agreement in accordance with section 1866(b)(2)(C) of the Act.

(F) The means by which the qualified entity may pay the amount if they do not intend to request a hearing.

(iii) *Failure to request a hearing.* If the qualified entity does not request a hearing within 60 days of receipt of the notice of proposed determination, any assessment becomes final and CMS may impose the proposed assessment.

(A) CMS notifies the qualified entity, by certified mail with return receipt requested, of any assessment that has been imposed and of the means by which the qualified entity may satisfy the judgment.

(B) The qualified entity has no right to appeal an assessment for which the qualified entity has not requested a hearing.

(iv) *When an assessment is collectible.* An assessment becomes collectible after the earliest of the following:

(A) Sixty (60) days after the qualified entity receives CMS's notice of proposed determination under paragraph (d)(5)(ii) of this section, if the qualified entity has not requested a hearing.

(B) Immediately after the qualified entity abandons or waives its appeal right at any administrative level.

(C) Thirty (30) days after the qualified entity receives the ALJ's decision imposing an assessment under § 1005.20(d) of this title, if the qualified entity has not requested a review before the DAB.

(D) Sixty (60) days after the qualified entity receives the DAB's decision imposing an assessment if the qualified entity has not requested a stay of the decision under § 1005.22(b) of this title.

(v) *Collection of an assessment.* Once a determination by HHS has become final, CMS is responsible for the collection of any assessment.

(A) The General Counsel may compromise an assessment imposed under this part, after consulting with CMS or OIG, and the Federal government may recover the assessment in a civil action brought in the United States district court for the district where the claim

was presented or where the qualified entity resides.

(B) The United States or a state agency may deduct the amount of an assessment when finally determined, or the amount agreed upon in compromise, from any sum then or later owing the qualified entity.

(C) 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 an assessment.

[76 FR 76567, Dec. 7, 2011, as amended at 81 FR 44481, July 7, 2016]

§ 401.721 Terminating an agreement with a qualified entity.

(a) *Grounds for terminating a qualified entity agreement.* CMS may terminate an agreement with a qualified entity if CMS determines the qualified entity or its contractor meets any of the following:

(1) Engages in one or more serious violations of the requirements of this subpart.

(2) Fails to completely and accurately report information to CMS or fails to make appropriate corrections in response to confidential reviews by providers and suppliers in a timely manner.

(3) Fails to submit an approvable corrective action plan (CAP) as prescribed by CMS, fails to implement an approved CAP, or fails to demonstrate improved performance after the implementation of a CAP.

(4) Improperly uses or discloses claims information received from CMS in violation of the requirements in this subpart.

(5) Based on its re-application, no longer meets the requirements in this subpart.

(6) Fails to maintain adequate data from other sources in accordance with § 401.711(c).

(7) Fails to ensure authorized users comply with their QE DUAs or analysis use agreements.

(b) *Return or destruction of CMS data upon voluntary or involuntary termination from the qualified entity program:*

(1) If CMS terminates a qualified entity's agreement, the qualified entity

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and its contractors must immediately upon receipt of notification of the termination commence returning or destroying any and all CMS data (and any derivative files). In no instance can this process exceed 30 days.

(2) If a qualified entity voluntarily terminates participation under this subpart, it and its contractors must return to CMS, or destroy, any and all CMS data in its possession within 30 days of notifying CMS of its intent to end its participation.

[76 FR 76567, Dec. 7, 2011, as amended at 81 FR 44482, July 7, 2016]

§ 401.722 Qualified clinical data registries.

(a) A qualified clinical data registry that agrees to meet all the requirements in this subpart, with the exception of § 401.707(d), may request access to Medicare data as a quasi qualified entity in accordance with such qualified entity program requirements.

(b) Notwithstanding § 401.703(q) (generally defining combined data), for purposes of qualified clinical data registries acting as quasi qualified entities under the qualified entity program requirements, combined data means, at a minimum, a set of CMS claims data provided under this subpart combined with clinical data or a subset of clinical data.

[81 FR 44482, July 7, 2016]

PART 402—CIVIL MONEY PENALTIES, ASSESSMENTS, AND EXCLUSIONS

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

SOURCE: 63 FR 68690, Dec. 14, 1998, unless otherwise noted.

Subpart A—General Provisions

§ 402.1 Basis and scope.

(a) *Basis.* This part is based on the sections of the Act that are specified in paragraph (c) of this section.

(b) *Scope.* This part—

(1) Provides for the imposition of civil money penalties, assessments, and exclusions against persons that violate the provisions of the Act specified in paragraph (c), (d), or (e) of this section; and

(2) Sets forth the appeal rights of persons subject to penalties, assessments, or exclusion and the procedures for reinstatement following exclusion.

(c) *Civil money penalties.* CMS or OIG may impose civil money penalties against any person or other entity specified in paragraphs (c)(1) through (c)(34) of this section under the identified section of the Act. (The authorities that also permit imposition of an assessment or exclusion are noted in the applicable paragraphs.)

(1) Sections 1833(h)(5)(D) and 1842(j)(2)—Any person that knowingly and willfully, and on a repeated basis, bills for a clinical diagnostic laboratory test, other than on an assignment-related basis. This provision includes tests performed in a physician's office but excludes tests performed in a rural health clinic. (This violation may also include an assessment and cause exclusion.)

(2) Section 1833(i)(6)—Any person that knowingly and willfully presents, or causes to be presented, a bill or request for payment for an intraocular lens inserted during or after cataract surgery for which the Medicare payment rate includes the cost of acquiring the class of lens involved.

(3) Section 1833(q)(2)(B)—Any entity that knowingly and willfully fails to provide information about a referring physician, including the physician's name and unique physician identification number for the referring physician, when seeking payment on an unassigned basis. (This violation, if it occurs in repeated cases, may also cause an exclusion.)

(4) Sections 1834(a)(11)(A) and 1842(j)(2)—Any durable medical equipment supplier that knowingly and willfully charges for a covered service that is furnished on a rental basis after the rental payments may no longer be made (except for maintenance and servicing) as provided in section 1834(a)(7)(A). (This violation may also include an assessment and cause exclusion.)

(5) Sections 1834(a)(18)(B) and 1842(j)(2)—Any nonparticipating durable medical equipment supplier that knowingly and willfully, in violation of section 1834(a)(18)(A), fails to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier. (This violation may also include an assessment and cause exclusion.)

(6) Sections 1834(b)(5)(C) and 1842(j)(2)—Any nonparticipating physician or supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge, as specified in section 1834(b)(5)(B), for radiologist services. (This violation

may also include an assessment and cause exclusion.)

(7) Sections 1834(c)(4)(C) and 1842(j)(2)—Any nonparticipating physician or supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge, as specified in section 1834(c)(4)(B), for mammography screening. (This violation may also include an assessment and cause exclusion.)

(8) Sections 1834(h)(3) and 1842(j)(2)—Any supplier of prosthetic devices, orthotics, and prosthetics that knowingly and willfully charges for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made (except for maintenance and servicing). (This violation may also include an assessment and cause exclusion.)

(9) Section 1834(j)(2)(A)(iii)—Any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully distributes a certificate of medical necessity in violation of section 1834(j)(2)(A)(i) or fails to provide the information required under section 1834(j)(2)(A)(ii).

(10) Sections 1834(j)(4) and 1842(j)(2)—

(i) Any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assignment-related basis if—

(A) The supplier does not possess a Medicare supplier number;

(B) The service is denied in advance under section 1834(a)(15); or

(C) The service is determined not to be medically necessary or reasonable.

(ii) These violations may also include an assessment and cause exclusion.

(11) Sections 1842(b)(18)(B) and 1842(j)(2)—Any practitioner specified in section 1842(b)(18)(C) (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, certified nurse-midwives, clinical social workers, and clinical psychologists) or other person that

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knowingly and willfully bills or collects for any services by the practitioners on other than an assignment-related basis. (This violation may also include an assessment and cause exclusion.)

(12) Sections 1842(k) and 1842(j)(2)—Any physician who knowingly and willfully presents, or causes to be presented, a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987 for which payment may not be made because of section 1862(a)(15). (This violation may also include an assessment and cause exclusion.)

(13) Sections 1842(l)(3) and 1842(j)(2)—Any nonparticipating physician who does not accept payment on an assignment-related basis and who knowingly and willfully fails to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality, in accordance with section 1842(l)(1)(A). (This violation may also include an assessment and cause exclusion.)

(14) Sections 1842(m)(3) and 1842(j)(2)—(i) Any nonparticipating physician, who does not accept payment for an elective surgical procedure on an assignment-related basis and whose charge is at least \$500, who knowingly and willfully fails to—

(A) Disclose the information required by section 1842(m)(1) concerning charges and coinsurance amounts; and

(B) Refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program.

(ii) This violation may also include an assessment and cause exclusion.

(15) Sections 1842(n)(3) and 1842(j)(2)—Any physician who knowingly and willfully, in repeated cases, bills one or more beneficiaries, for purchased diagnostic tests, any amount other than the payment amount specified in section 1842(n)(1)(A) or section 1842(n)(1)(B). (This violation may also include an assessment and cause exclusion.)

(16) Section 1842(p)(3)(A)—Any physician or practitioner who knowingly and willfully fails promptly to provide the appropriate diagnosis code or codes upon request by CMS or a carrier on any request for payment or bill not

submitted on an assignment-related basis for any service furnished by the physician. (This violation, if it occurs in repeated cases, may also cause exclusion.)

(17) Sections 1848(g)(1)(B) and 1842(j)(2)—

(i) Any nonparticipating physician, supplier, or other person that furnishes physicians' services and does not accept payment on an assignment-related basis, that—

(A) Knowingly and willfully bills or collects in excess of the limiting charge (as defined in section 1848(g)(2)) on a repeated basis; or

(B) Fails to make an adjustment or refund on a timely basis as required by section 1848(g)(1)(A)(iii) or (iv).

(ii) These violations may also include an assessment and cause exclusion.

(18) Section 1848(g)(3)(B) and 1842(j)(2)—Any person that knowingly and willfully bills for State plan approved physicians' services, as defined in section 1848(j)(3), on other than an assignment-related basis for a Medicare beneficiary who is also eligible for Medicaid (these individuals include qualified Medicare beneficiaries). This provision applies to services furnished on or after April 1, 1990. (This violation may also include an assessment and cause exclusion.)

(19) Section 1848(g)(4)(B)(ii), 1842(p)(3), and 1842(j)(2)(A)—

(i) Any physician, supplier, or other person (except any person that has been excluded from the Medicare program) that, for services furnished after September 1, 1990, knowingly and willfully—

(A) Fails to submit a claim on a standard claim form for services provided for which payment is made under Part B on a reasonable charge or fee schedule basis; or

(B) Imposes a charge for completing and submitting the standard claims form.

(ii) These violations, if they occur in repeated cases, may also cause exclusion.

(20) Section 1862(b)(5)(C)—Any employer (other than a Federal or other governmental agency) that, before October 1, 1998, willfully or repeatedly

fails to provide timely and accurate information requested relating to an employee's group health insurance coverage.

(21) Section 1862(b)(6)(B)—Any entity that knowingly, willfully, and repeatedly—

(i) Fails to complete a claim form relating to the availability of other health benefit plans in accordance with section 1862(b)(6)(A); or

(ii) Provides inaccurate information relating to the availability of other health benefit plans on the claim form.

(22) Section 1877(g)(5)—Any person that fails to report information required by HHS under section 1877(f) concerning ownership, investment, and compensation arrangements. (This violation may also include an assessment and cause exclusion.)

(23) Sections 1879(h), 1834(a)(18), and 1842(j)(2)—

(i) Any durable medical equipment supplier, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for services billed on an assignment-related basis if—

(A) The supplier did not possess a Medicare supplier number;

(B) The service is denied in advance under section 1834(a)(15) of the Act; or

(C) The service is determined not to be payable under section 1834(a)(17)(b) because of unsolicited telephone contacts.

(ii) These violations may also include an assessment and cause exclusion.

(24) Section 1882(a)(2)—Any person that issues a Medicare supplemental policy that has not been approved by the State regulatory program or does not meet Federal standards on and after the effective date in section 1882(p)(1)(C). (This violation may also include an assessment and cause exclusion.)

(25) Section 1882(p)(8)—Any person that sells or issues Medicare supplemental policies, on or after July 30, 1992, that fail to conform to the NAIC or Federal standards established under section 1882(p). (This violation may also include an assessment and cause exclusion.)

(26) Section 1882(p)(9)(C)—

(i) Any person that sells a Medicare supplemental policy and—

(A) Fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits; or

(B) Fails to provide the individual, before the sale of the policy, an outline of coverage describing the benefits provided by the policy.

(ii) These violations may also include an assessment and cause exclusion.

(27) Section 1882(q)(5)(C)—

(i) Any person that fails to—

(A) Suspend a Medicare supplemental policy at the policyholder's request, if the policyholder applies for and is determined eligible for medical assistance, and the policyholder provides notice within 90 days of the eligibility determination; or

(B) Automatically reinstate the policy as of the date of termination of medical assistance if the policyholder loses eligibility for medical assistance and the policyholder provides notice within 90 days of loss of eligibility.

(ii) These violations may also include an assessment and cause exclusion.

(28) Section 1882(r)(6)(A)—Any person that fails to provide refunds or credits as required by section 1882(r)(1)(B). (This violation may also include an assessment and cause exclusion.)

(29) Section 1882(s)(4)—

(i) Any issuer of a Medicare supplemental policy that—

(A) Does not waive any time periods applicable to preexisting conditions, waiting periods, elimination periods, or probationary periods if the time periods were already satisfied under a preceding Medicare supplemental policy; or

(B) Denies a policy, conditions the issuance or effectiveness of the policy, or discriminates in the pricing of the policy based on health status or other criteria as specified in section 1882(s)(2)(A).

(ii) These violations may also include an assessment and cause exclusion.

(30) Section 1882(t)(2)—

(i) Any issuer of a Medicare supplemental policy that—

(A) Fails substantially to provide medically necessary services to enrollees seeking the services through the issuer's network of entities;

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(B) Imposes premiums on enrollees in excess of the premiums approved by the State;

(C) Acts to expel an enrollee for reasons other than nonpayment of premiums; or

(D) Does not provide each enrollee at the time of enrollment with the specific information provided in section 1882(t)(1)(E)(i) or fails to obtain a written acknowledgment from the enrollee of receipt of the information (as required by section 1882(t)(1)(E)(ii)).

(ii) These violations may also include an assessment and cause exclusion.

(31) Sections 1834(k)(6) and 1842(j)(2)—Any person or entity who knowingly and willfully bills or collects for any outpatient therapy services or comprehensive outpatient rehabilitation services on other than an assignment-related basis. (This violation may also include an assessment and cause exclusion.)

(32) Sections 1834(l)(6) and 1842(j)(2)—Any supplier of ambulance services who knowingly and willfully bills or collects for any services on other than an assignment-related basis. (This violation may also include an assessment and cause exclusion.)

(33) Section 1806(b)(2)(B)—Any person who knowingly and willfully fails to furnish a beneficiary with an itemized statement of items or services within 30 days of the beneficiary's request.

(34) Section 1128G (b) (1) and (2)—Any applicable manufacturer or applicable group purchasing organization that fails to timely, accurately, or completely report a payment or other transfer of value or an ownership or investment interest to CMS, as required under part 403, subpart I, of this chapter.

(d) *Assessments.* CMS or OIG may impose assessments in addition to civil money penalties for violations of the following statutory sections:

(1) Section 1833: Paragraph (h)(5)(D).

(2) Section 1834: Paragraphs (a)(11)(A), (a)(18)(B), (b)(5)(C), (c)(4)(C), (h)(3), (j)(4), (k)(6), and (l)(6).

(3) Section 1842: Paragraphs (k), (l)(3), (m)(3), and (n)(3).

(4) Section 1848: Paragraph (g)(1)(B).

(5) Section 1877: Paragraph (g)(5).

(6) Section 1879: Paragraph (h).

(7) Section 1882: Paragraphs (a)(2), (p)(8), (p)(9)(C), (q)(5)(C), (r)(6)(A), (s)(3), and (t)(2).

(e) *Exclusions.* (1) CMS or OIG may exclude any person from participation in the Medicare program on the basis of any of the following violations of the statute:

(i) Section 1833: Paragraphs (h)(5)(D) and, in repeated cases, (q)(2)(B).

(ii) Section 1834: Paragraphs (a)(11)(A), (a)(18)(B), (b)(5)(C), (c)(4)(C), (h)(3), (j)(4), (k)(6), and (l)(6).

(iii) Section 1842: Paragraphs (b)(18)(B), (k), (l)(3), (m)(3), (n)(3), and, in repeated cases, (p)(3)(B).

(iv) Section 1848: Paragraphs (g)(1)(B), (g)(3)(B), and, in repeated cases, (g)(4)(B)(ii).

(v) Section 1877: Paragraph (g)(5).

(vi) Section 1879: Paragraph (h).

(vii) Section 1882: Paragraphs (a)(2), (p)(8), (p)(9)(C), (q)(5)(C), (r)(6)(A), (s)(4), and (t)(2).

(2) CMS or OIG must exclude from participation in the Medicare program any of the following, under the identified section of the Act:

(i) Section 1834(a)(17)(C)—Any supplier of durable medical equipment and supplies that are covered under section 1834(a)(13) that knowingly contacts Medicare beneficiaries by telephone regarding the furnishing of covered services in violation of section 1834(a)(17)(A) and whose conduct establishes a pattern of prohibited contacts as described under section 1834(a)(17)(A).

(ii) Section 1834(h)(3)—Any supplier of prosthetic devices, orthotics, and prosthetics that knowingly contacts Medicare beneficiaries by telephone regarding the furnishing of prosthetic devices, orthotics, or prosthetics in the same manner as in the violation under section 1834(a)(17)(A) and whose conduct establishes a pattern of prohibited contacts in the same manner as described in section 1834(a)(17)(C).

(f) *Responsible persons.* (1) If CMS or OIG determines that more than one person is responsible for any of the violations described in paragraph (c) or paragraph (d) of this section, it may impose a civil money penalty or a civil money penalty and assessment against any one of those persons or jointly and severally against two or more of those

persons. However, the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person were responsible.

(2) A principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of the agency.

(g) *Time limits.* Neither CMS nor OIG initiates an action to impose a civil money penalty, assessment, or proceeding to exclude a person from participation in the Medicare program unless it begins the action within 6 years from the date on which the claim was presented, the request for payment was made, or the incident occurred.

[63 FR 68690, Dec. 14, 1998, as amended at 66 FR 49546, Sept. 28, 2001; 78 FR 9520, Feb. 8, 2013]

§ 402.3 Definitions.

For purposes of this part:

Assessment means the amount described in § 402.107 and includes the plural of that term.

Assignment-related basis means that the claim submitted by a physician, supplier or other person is paid on the basis of an assignment, whereby the physician, supplier or other person agrees to accept the Medicare payment as payment in full for the services furnished to the beneficiary and is precluded from charging the beneficiary more than the deductible and coinsurance based upon the approved Medicare fee amount. Additional obligations, including obligations to make refunds in certain circumstances, are established at section 1842(b)(3) of the Act.

Claim means an application for payment for a service for which the Medicare or Medicaid program may pay.

Covered means that a service is described as reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. A service is not covered if it is specifically identified as excluded from Medicare Part B coverage or is not a defined Medicare Part B benefit.

Exclusion means the temporary or permanent barring of a person or other entity from participation in the Medicare or State health care program and that services furnished or ordered by

that person are not paid for under either program.

General Counsel means the General Counsel of HHS or his or her designees.

Initiating agency means whichever agency (CMS or the OIG) initiates the interaction with the person.

Knowingly or knowingly and willfully means that a person, with respect to information—

(1) Has actual knowledge of the information;

(2) Acts in deliberate ignorance of the truth or falsity of the information; or

(3) Acts in reckless disregard of the truth or falsity of the information; and

(4) No proof of specific intent is required.

Medicare supplemental policy means a policy guaranteeing that a health plan will pay a policyholder's coinsurance and deductible and will cover other limitations on payment imposed under title XVIII of the Act and will provide additional health plan or non-Medicare coverage for services up to a predefined benefit limit.

NAIC stands for the National Association of Insurance Commissioners.

Nonparticipating describes a physician, supplier, or other person (excluding any provider of services) that, at the time of furnishing the services to Medicare Part B beneficiaries, is not a participating physician or supplier.

Participating describes a physician or supplier (excluding any provider of services) that, before the beginning of any given year, enters into an agreement with HHS that provides that the physician or supplier will accept payment under the Medicare program on an assignment-related basis for all services furnished to Medicare Part B beneficiaries.

Penalty means the amount described in § 402.105 and includes the plural of that term.

Person means an individual, trust or estate, partnership, corporation, professional association or corporation, or other entity, public or private.

Physicians' services means the following Medicare covered professional services:

(1) Surgery, consultation, home, office and institutional calls, and other professional services performed by physicians.

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(2) Services and supplies furnished “incident to” a physician’s professional services.

(3) Outpatient physical and occupational therapy services.

(4) Diagnostic x-ray tests and other diagnostic tests (excluding clinical diagnostic laboratory tests).

(5) X-ray, radium, and radioactive isotope therapy, including materials and services of technicians.

(6) Antigens prepared by a physician.

Radiologist service means radiology services performed only by, or under the direction of, a physician who is certified, or eligible to be certified, by the American Board of Radiology or for whom radiology services account for at least 50 percent of the total amount of charges made under part B of title XVIII of the Act.

Request for payment means an application submitted by a person to any person for payment for a service.

Respondent means the person upon which CMS or OIG has imposed, or proposes to impose, a civil money penalty, assessment, or exclusion.

Service includes—

(1) Any item, device, medical supply, or service claimed to have been furnished to a patient and listed in an itemized claim for program payment; or

(2) In the case of a claim based on costs, any entry or omission in a cost report, books of account or other documents supporting the claim.

State includes the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands.

Timely basis means that the adjustment to a bill or a refund is considered “on a timely basis” if the physician, supplier, or other person makes the adjustment or refund to the appropriate party no later than 30 days after the date the physician, supplier, or other person is notified by the Medicare Part B contractor of the violation and the requirement to refund any excess collections.

[63 FR 68690, Dec. 14, 1998, as amended at 72 FR 39752, July 20, 2007]

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§ 402.5 Right to a hearing before the final determination.

CMS or OIG does not make a determination adverse to any person under this part until the person has been given a written notice and opportunity for the determination to be made on the record after a hearing at which the person is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses against the person.

§ 402.7 Notice of proposed determination.

(a) If CMS or OIG proposes a penalty and, as applicable, an assessment, or proposes to exclude a respondent from participation in Medicare in accordance with this part, it sends the respondent written notice of its intent by certified mail, return receipt requested. The notice includes the following information:

(1) Reference to the statutory basis or bases for the penalty, assessment, exclusion, or any combination, as applicable.

(2)(i) A description of the claims, requests for payment, or incidents with respect to which the penalty, assessment, and exclusion are proposed; or

(ii) If CMS or OIG is relying upon statistical sampling to project the number and types of claims or requests for payment and the dollar amount, a description of the claims and requests for payment comprising the sample and a brief description of the statistical sampling technique CMS or OIG used.

(3) The reason why the claims, requests for payment, or incidents are subject to a penalty and assessment.

(4) The amount of the proposed penalty and of any proposed assessment.

(5) Any mitigating or aggravating circumstances that CMS or OIG considered when it determined the amount of the proposed penalty and any applicable assessment.

(6) Information concerning response to the notice, including—

(i) A specific statement of the respondent’s right to a hearing; and

(ii) A statement that failure to request a hearing within 60 days renders the proposed determination final and permits the imposition of the proposed penalty and any assessment.

(iii) A statement that the debt may be collected through an administrative offset.

(7) In the case of a respondent that has an agreement under section 1866 of the Act, notice that imposition of an exclusion may result in termination of the provider's agreement in accordance with section 1866(b)(2)(C) of the Act.

§ 402.9 Failure to request a hearing.

(a) If the respondent does not request a hearing within 60 days of receipt of the notice of proposed determination specified in § 402.7, any civil money penalty, assessment, or exclusion becomes final and CMS or OIG may impose the proposed penalty, assessment, or exclusion, or any less severe penalty, assessment, or suspension.

(b) CMS or OIG notifies the respondent by certified mail, return receipt requested, of any penalty, assessment, or exclusion that has been imposed and of the means by which the respondent may satisfy the judgment.

(c) The respondent has no right to appeal a penalty, assessment, or exclusion for which he or she has not requested a hearing.

§ 402.11 Notice to other agencies and other entities.

(a) Whenever a penalty, assessment, or exclusion becomes final, CMS or OIG notifies the following organizations and entities about the action and the reasons for it:

(1) The appropriate State or local medical or professional association.

(2) The appropriate quality improvement organization.

(3) As appropriate, the State agency responsible for the administration of each State health care program (Medicaid, the Maternal and Child Health Services Block Grant Program, and the Social Services Block Grant Program).

(4) The appropriate Medicare carrier or fiscal intermediary.

(5) The appropriate State or local licensing agency or organization (including the Medicare and Medicaid State survey agencies).

(6) The long-term care ombudsman.

(b) For exclusions, CMS or OIG also notifies the public and specifies the effective date.

§ 402.13 Penalty, assessment, and exclusion not exclusive.

Penalties, assessments, and exclusions imposed under this part are in addition to any other penalties prescribed by law.

§ 402.15 Collateral estoppel.

(a) When a final determination that the respondent presented or caused to be presented a claim or request for payment falling within the scope of § 402.1 has been rendered in any proceeding in which the respondent was a party and had an opportunity to be heard, the respondent is bound by that determination in any proceeding under this part.

(b) A person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements is barred from denying the essential elements of the criminal offense if the proceedings under this part involve the same transactions.

§ 402.17 Settlement.

CMS or OIG has exclusive authority to settle any issues or case, without the consent of the ALJ or the Secretary, at any time before a final decision by the Secretary. Thereafter, the General Counsel has the exclusive authority.

§ 402.19 Hearings and appeals.

The hearings and appeals procedures set forth in part 1005 of chapter V of this title are available to any person that receives an adverse determination under this part. For an appeal of a civil money penalty, assessment, or exclusion imposed under this part, either CMS or OIG may represent the government in the hearing and appeals process.

§ 402.21 Judicial review.

After exhausting all available administrative remedies, a respondent may seek judicial review of a penalty, assessment, or exclusion that has become final. The respondent may seek review only with respect to a penalty, assessment, or exclusion with respect to

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which the respondent filed an exception under § 1005.21(c) of this title unless the court excuses the failure or neglect to urge the exception in accordance with section 1128A(e) of the Act because of extraordinary circumstances.

Subpart B—Civil Money Penalties and Assessments

§ 402.105 Amount of penalty.

(a) *\$2,000.* Except as provided in paragraphs (b) through (h) of this section, CMS or OIG may impose a penalty of not more than \$2,000 as adjusted annually under 45 CFR part 102 for each service, bill, or refusal to issue a timely refund that is subject to a determination under this part and for each incident involving the knowing, willful, and repeated failure of an entity furnishing a service to submit a properly completed claim form or to include on the claim form accurate information regarding the availability of other health insurance benefit plans (§ 402.1(c)(21)).

(b) *\$1,000.* CMS or OIG may impose a penalty of not more than \$1,000 as adjusted annually under 45 CFR part 102 for the following:

(1) Per certificate of medical necessity knowingly and willfully distributed to physicians on or after December 31, 1994 that—

- (i) Contains information concerning the medical condition of the patient; or
- (ii) Fails to include cost information.

(2) Per individual about whom information is requested, for willful or repeated failure of an employer to respond to an intermediary or carrier about coverage of an employee or spouse under the employer's group health plan (§ 402.1(c)(20)).

(c) *\$5,000.* CMS or OIG may impose a penalty of not more than \$5,000 as adjusted annually under 45 CFR part 102 for each violation resulting from the following:

(1) The failure of a Medicare supplemental policy issuer, on a replacement policy, to waive any time periods applicable to pre-existing conditions, waiting periods, elimination periods, or probationary periods that were satisfied under a preceding policy (§ 402.1(c)(29)); and

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(2) Any issuer of any Medicare supplemental policy denying a policy, conditioning the issuance or effectiveness of the policy, or discriminating in the pricing of the policy based on health status or other criteria as specified in section 1882(s)(2)(A). (§ 402.1(c)(29)).

(d) *\$10,000.* (1) CMS or OIG may impose a penalty of not more than \$10,000 as adjusted annually under 45 CFR part 102 for each day that reporting entity ownership arrangements is late (§ 402.1(c)(22)).

(2) CMS or OIG may impose a penalty of not more than \$10,000 as adjusted annually under 45 CFR part 102 for the following violations that occur on or after January 1, 1997:

(i) Knowingly and willfully, and on a repeated basis, billing for a clinical diagnostic laboratory test, other than on an assignment-related basis (§ 402.1(c)(1)).

(ii) By any durable medical equipment supplier, knowingly and willfully charging for a covered service that is furnished on a rental basis after the rental payments may no longer be made (except for maintenance and servicing) as provided in section 1834(a)(7)(A) (§ 402.1(c)(4)).

(iii) By any durable medical equipment supplier, knowingly and willfully, in violation of section 1834(a)(18)(A), failing to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier (§ 402.1(c)(5)).

(iv) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(b)(5)(B), for radiologist services (§ 402.1(c)(6)).

(v) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(c)(3), for mammography screening (§ 402.1(c)(7)).

(vi) By any supplier of prosthetic devices, orthotics, and prosthetics, knowingly and willfully charging for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made (except for maintenance and servicing) (§ 401.2(c)(8)).

(vii) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assigned-related basis if—

(A) The supplier does not possess a Medicare supplier number;

(B) The service is denied in advance; or

(C) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(10)).

(viii) Knowingly and willfully billing or collecting for any services on other than an assignment-related basis for practitioners specified in section 1842(b)(18)(B) (§ 402.1(c)(11)).

(ix) By any physician, knowingly and willfully presenting, or causing to be presented, a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987 for which payment may not be made because of section 1862(a)(15) (§ 402.1(c)(12)).

(x) By any nonparticipating physician who does not accept payment on an assignment-related basis, knowingly and willfully failing to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality, in accordance with section 1842(l)(1)(A) (§ 402.1(c)(13)).

(xi) By any nonparticipating physician, who does not accept payment for an elective surgical procedure on an assignment-related basis and whose charge is at least \$500, knowingly and willfully failing to—

(A) Disclose the information required by section 1842(m)(1) concerning charges and coinsurance amounts; and

(B) Refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program (§ 402.1(c)(14)).

(xii) By any physician, in repeated cases, knowingly and willfully billing one or more beneficiaries, for purchased diagnostic tests, any amount other than the payment amount specified in section 1842(n)(1)(A) or section 1842(n)(1)(B) (§ 402.1(c)(15)).

(xiii) By any nonparticipating physician, supplier, or other person that fur-

nishes physicians' services and does not accept payment on an assignment-related basis—

(A) Knowingly and willfully billing or collecting in excess of the limiting charge (as defined in section 1843(g)(2)) on a repeated basis; or

(B) Failing to make an adjustment or refund on a timely basis as required by section 1848(g)(1)(A)(iii) or (iv) (§ 402.1(c)(17)).

(xiv) Knowingly and willfully billing for State plan approved physicians' services on other than an assignment-related basis for a Medicare beneficiary who is also eligible for Medicaid (§ 402.1(c)(18)).

(xv) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed on an assignment-related basis if—

(A) The supplier did not possess a Medicare supplier number;

(B) The service is denied in advance; or

(C) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(23)).

(3) CMS or OIG may impose a penalty of not more than \$10,000 as adjusted annually under 45 CFR part 102 for each violation, if a person or entity knowingly and willfully bills or collects for outpatient therapy or comprehensive rehabilitation services other than on an assignment-related basis.

(4) CMS or OIG may impose a penalty of not more than \$10,000 as adjusted annually under 45 CFR part 102 for each violation, if a person or entity knowingly and willfully bills or collects for outpatient ambulance services other than on an assignment-related basis.

(5) CMS or OIG may impose a penalty of not more than \$10,000 as adjusted annually under 45 CFR part 102 for each failure of an applicable manufacturer or an applicable group purchasing organization to report timely, accurately, or completely a payment or other transfer of value or an ownership or investment interest (§ 402.1(c)(34)). The total penalty imposed with respect to failures to report in an annual submission of information will not exceed

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\$150,000 as annually adjusted under 45 CFR part 102.

(e) *\$15,000.* CMS or OIG may impose a penalty of not more than \$15,000 as adjusted annually under 45 CFR part 102 for if the seller of a Medicare supplemental policy is not the issuer, for each violation described in paragraphs (f)(2) and (f)(3) of this section (§ 402.1(c)(25) and (c)(26)).

(f) *\$25,000.* CMS or OIG may impose a penalty of not more than \$25,000 as adjusted annually under 45 CFR part 102 for each of the following violations:

(1) Issuance of a Medicare supplemental policy that has not been approved by an approved State regulatory program or does not meet Federal standards on and after the effective date in section 1882(p)(1)(C) of the Act (§ 402.1(c)(23)).

(2) Sale or issuance after July 30, 1992, of a Medicare supplemental policy that fails to conform with the NAIC or Federal standards established under section 1882(p) of the Act (§ 402.1(c)(25)).

(3) Failure to make the core group of basic benefits available for sale when selling other Medicare supplemental plans with additional benefits (§ 402.1(c)(26)).

(4) Failure to provide, before sale of a Medicare supplemental policy, an outline of coverage describing the benefits provided by the policy (§ 402.1(c)(26)).

(5) Failure of an issuer of a policy to suspend or reinstate a policy, based on the policy holder's request, during entitlement to or upon loss of eligibility for medical assistance (§ 402.1(c)(27)).

(6) Failure to provide refunds or credits for Medicare supplemental policies as required by section 1882(r)(1)(B) (§ 402.1(c)(28)).

(7) By an issuer of a Medicare supplemental policy—

(i) Substantial failure to provide medically necessary services to enrollees seeking the services through the issuer's network of entities;

(ii) Imposition of premiums on enrollees in excess of the premiums approved by the State;

(iii) Action to expel an enrollee for reasons other than nonpayment of premiums; or

(iv) Failure to provide each enrollee, at the time of enrollment, with the specific information provided in sec-

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tion 1882(t)(1)(E)(i) or failure to obtain a written acknowledgment from the enrollee of receipt of the information (as required by section 1882(t)(1)(E)(ii)) (section 1882(t)(2)).

(g) *\$100.* CMS or OIG may impose a penalty of not more than \$100 as adjusted annually under 45 CFR part 102 for each violation if the person or entity does not furnish an itemized statement to a Medicare beneficiary within 30 days of the beneficiary's request.

(h) *\$100,000.* CMS or OIG may impose a penalty of not more than \$10,000 as adjusted annually under 45 CFR part 102 for each knowing failure of an applicable manufacturer or an applicable group purchasing organization to report timely, accurately or completely a payment or other transfer of value or an ownership or investment interest (§ 402.1(c)(34)). The total penalty imposed with respect to knowing failures to report in an annual submission of information will not exceed \$1,000,000 as annually adjusted under 45 CFR part 102.

[63 FR 68690, Dec. 14, 1998, as amended at 66 FR 49546, Sept. 28, 2001; 72 FR 39752, July 20, 2007; 72 FR 46175, Aug. 17, 2007; 78 FR 9520, Feb. 8, 2013; 81 FR 61561, Sept. 6, 2016]

§ 402.107 Amount of assessment.

A person subject to civil money penalties specified in § 402.1(c) may be subject, in addition, to an assessment. An assessment is a monetary payment in lieu of damages sustained by HHS or a State agency.

(a) The assessment may not be more than twice the amount claimed for each service that was a basis for the civil money penalty, except for the violations specified in paragraph (b) of this section that occur before January 1, 1997.

(b) For the violations specified in this paragraph occurring after January 1, 1997, the assessment may not be more than three times the amount claimed for each service that was the basis for a civil money penalty. The violations are the following:

(1) Knowingly and willfully billing, and on a repeated basis, for a clinical diagnostic laboratory test, other than on an assignment-related basis (§ 402.1(c)(1)).

(2) By any durable medical equipment supplier, knowingly and willfully charging for a covered service that is furnished on a rental basis after the rental payments may no longer be made (except for maintenance and servicing) as provided in section 1834(a)(7)(A) (§ 402.1(c)(4)).

(3) By any durable medical equipment supplier, knowingly and willfully failing, in violation of section 1834(a)(18)(A), to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier (§ 402.1(c)(5)).

(4) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge, as specified in section 1834(b)(5)(B), for radiologist services (§ 402.1(c)(6)).

(5) By any nonparticipating physician or supplier, knowingly and willfully charging a Medicare beneficiary more than the limiting charge as specified in section 1834(c)(3), for mammography screening (§ 402.1(c)(7)).

(6) By any supplier of prosthetic devices, orthotics, and prosthetics, knowingly and willfully charging for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made (except for maintenance and servicing) (§ 401.2(c)(8)).

(7) By any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a timely manner to Medicare beneficiaries for services billed other than on an assignment-related basis if—

(i) The supplier does not possess a Medicare supplier number;

(ii) The service is denied in advance; or

(iii) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(10)).

(8) Knowingly and willfully billing or collecting for any services on other than an assignment-related basis for a person or entity specified in sections 1834(k)(6), 1834(l)(6), or 1842(b)(18)(B) (§ 402.1(c)(11), (c)(31), or (c)(32)).

(9) By any physician, knowingly and willfully presenting, or causing to be

presented, a claim or bill for an assistant at cataract surgery performed on or after March 1, 1987 for which payment may not be made because of section 1862(a)(15) (§ 402.1(c)(12)).

(10) By any nonparticipating physician who does not accept payment on an assignment-related basis, knowingly and willfully failing to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality, in accordance with section 1842(l)(1)(A) (§ 402.1(c)(13)).

(11) By any nonparticipating physician, who does not accept payment for an elective surgical procedure on an assignment-related basis and whose charge is at least \$500, knowingly and willfully failing to—

(i) Disclose the information required by section 1842(m)(1) concerning charges and coinsurance amounts; and

(ii) Refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program (§ 402.1(c)(14)).

(12) By any physician, in repeated cases, knowingly and willfully billing one or more beneficiaries, for purchased diagnostic tests, any amount other than the payment amount specified in section 1842(n)(1)(A) or section 1842(n)(1)(B) (§ 402.1(c)(15)).

(13) By any nonparticipating physician, supplier, or other person that furnishes physicians' services and does not accept payment on an assignment-related basis—

(i) Knowingly and willfully billing or collecting in excess of the limiting charge (as defined in section 1843(g)(2)) on a repeated basis; or

(ii) Failing to make an adjustment or refund on a timely basis as required by section 1848(g)(1)(A) (iii) or (iv) (§ 402.1(c)(17)).

(14) Knowingly and willfully billing for State plan approved physicians' services on other than an assignment-related basis for a Medicare beneficiary who is also eligible for Medicaid (§ 402.1(c)(18)).

(15) By any supplier of durable medical equipment, including suppliers of prosthetic devices, prosthetics, orthotics, or supplies, knowingly and willfully failing to make refunds in a

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timely manner to Medicare beneficiaries for services billed on an assignment-related basis if—

- (i) The supplier did not possess a Medicare supplier number;
- (ii) The service is denied in advance; or
- (iii) The service is determined not to be medically necessary or reasonable (§ 402.1(c)(23)).

[63 FR 68690, Dec. 14, 1998, as amended at 66 FR 49546, Sept. 28, 2001]

§ 402.109 Statistical sampling.

(a) *Purpose.* CMS or OIG may introduce the results of a statistical sampling study to show the number and amount of claims subject to sanction under this part that the respondent presented or caused to be presented.

(b) *Prima facie evidence.* The results of the statistical sampling study, if based upon an appropriate sampling and computed by valid statistical methods, constitute prima facie evidence of the number and amount of claims or requests for payment subject to sanction under § 402.1.

(c) *Burden of proof.* Once CMS or OIG has made a prima facie case, the burden is on the respondent to produce evidence reasonably calculated to rebut the findings of the statistical sampling study. CMS or OIG then has the opportunity to rebut this evidence.

§ 402.111 Factors considered in determinations regarding the amount of penalties and assessments.

(a) *Basic factors.* In determining the amount of any penalty or assessment, CMS or OIG takes into account the following:

- (1) The nature of the claim, request for payment, or information given and the circumstances under which it was presented or given.
- (2) The degree of culpability, history of prior offenses, and financial condition of the person submitting the claim or request for payment or giving the information.
- (3) The resources available to the person submitting the claim or request for payment or giving the information.
- (4) Such other matters as justice may require.

(b) *Criteria to be considered.* As guidelines for taking into account the fac-

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tors listed in paragraph (a) of this section, CMS or OIG considers the following circumstances:

(1) *Aggravating circumstances of the incident.* An aggravating circumstance is any of the following:

(i) The services or incidents were of several types, occurring over a lengthy period of time.

(ii) There were many of these services or incidents or the nature and circumstances indicate a pattern of claims or requests for payment for these services or a pattern of incidents.

(iii) The amount claimed or requested for these services was substantial.

(iv) Before the incident or presentation of any claim or request for payment subject to imposition of a civil money penalty, the respondent was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services.

(v) There is proof that a respondent engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to government programs or in connection with the delivery of a health care service. (The statute of limitations governing civil money penalty proceedings does not apply to proof of other wrongful conduct as an aggravating circumstance.)

(2) *Mitigating circumstances.* The following circumstances are mitigating circumstances:

(i) All the services or incidents subject to a civil money penalty were few in number and of the same type, occurred within a short period of time, and the total amount claimed or requested for the services was less than \$1,000.

(ii) The claim or request for payment for the service was the result of an unintentional and unrecognized error in the process of presenting claims or requesting payment and the respondent took corrective steps promptly after discovering the error.

(iii) Imposition of the penalty or assessment without reduction would jeopardize the ability of the respondent to continue as a health care provider.

(3) *Other matters as justice may require.* Other circumstances of an aggravating or mitigating nature are taken into account if, in the interests of justice, they require either a reduction of the penalty or assessment or an increase in order to ensure the achievement of the purposes of this part.

(c) *Effect of aggravating or mitigating circumstances.* In determining the amount of the penalty and assessment to be imposed for every service or incident subject to a determination under § 402.1(c)—

(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment is set at an amount sufficiently below the maximum permitted by §§ 402.105(a) and 402.107 to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment is set at an amount at or sufficiently close to the maximum permitted by §§ 402.105(a) and 402.107 to reflect that fact.

(d)(1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.

(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 imposed 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

SOURCE: 72 FR 39752, July 20, 2007, unless otherwise noted.

§ 402.200 Basis and purpose.

(a) *Basis.* This subpart is based on the sections of the Act that are specified in § 402.1(e).

(b) *Purpose.* This subpart—

- (1) Provides for the imposition of an exclusion from the Medicare and Medicaid programs (and, where applicable, other Federal health care programs) against persons that violate the provisions of the Act provided in § 402.1(e) (and further described in § 402.1(c)); and
- (2) Sets forth the appeal rights of persons subject to exclusion and the procedures for reinstatement following exclusion.

§ 402.205 Length of exclusion.

The length of exclusion from participation in Medicare, Medicaid, and, where applicable, other Federal health care programs, is contingent upon the specific violation of the Medicare statute. A full description of the specific violations identified in the sections of the Act are cross-referenced in the regulatory sections listed in the table in paragraph (a) of this section.

(a) In no event will the period of exclusion exceed 5 years for violation of the following sections of the Act:

Social Security Act paragraph	Code of Federal Regulations section
1833(h)(5)(D) in repeated cases	§ 402.1(c)(1)
1833(q)(2)(B) in repeated cases	§ 402.1(c)(3)
1834(a)(11)(A)	§ 402.1(c)(4)
1834(a)(18)(B)	§ 402.1(c)(5)
1834(b)(5)(C)	§ 402.1(c)(6)
1834(c)(4)(C)	§ 402.1(c)(7)
1834(h)(3)	§ 402.1(c)(8)
1834(j)(4)	§ 402.1(c)(10)
1834(k)(6)	§ 402.1(c)(31)
1834(l)(6)	§ 402.1(c)(32)
1842(b)(18)(B)	§ 402.1(c)(11)
1842(k)	§ 402.1(c)(12)
1842(l)(3)	§ 402.1(c)(13)
1842(m)(3)	§ 402.1(c)(14)
1842(n)(3)	§ 402.1(c)(15)
1842(p)(3)(B) in repeated cases	§ 402.1(c)(16)
1848(g)(1)(B) in repeated cases	§ 402.1(c)(17)
1848(g)(3)(B)	§ 402.1(c)(18)
1848(g)(4)(B)(ii) in repeated cases	§ 402.1(c)(19)
1879(h)	§ 402.1(c)(23)

(b) For violation of the following sections, there is no maximum time limit for the period of exclusion.

Social Security Act paragraph	Code of Federal Regulations section
1834(a)(17)(c) for a pattern of contacts.	§ 402.1(e)(2)(i)
1834(h)(3) for a pattern of contacts	§ 402.1(e)(2)(ii)
1877(g)(5)	§ 402.1(c)(22)
1882(a)(2)	§ 402.1(c)(24)
1882(p)(8)	§ 402.1(c)(25)
1882(p)(9)(C)	§ 402.1(c)(26)
1882(q)(5)(C)	§ 402.1(c)(27)
1882(r)(6)(A)	§ 402.1(c)(28)
1882(s)(4)	§ 402.1(c)(29)
1882(t)(2)	§ 402.1(c)(30)

(c) For a person excluded under any of the grounds specified in paragraph (a) of this section, notwithstanding any other requirements in this section, reinstatement occurs—

- (1) At the expiration of the period of exclusion, if the exclusion was imposed for a period of 5 years; or
- (2) At the expiration of 5 years from the effective date of the exclusion, if the exclusion was imposed for a period of less than 5 years and the initiating agency did not receive the appropriate written request for reinstatement as specified in § 402.300.

§ 402.208 Factors considered in determining whether to exclude, and the length of exclusion.

(a) *General factors.* In determining whether to exclude a person and the length of exclusion, the initiating agency considers the following:

- (1) The nature of the claims and the circumstances under which they were presented.
- (2) The degree of culpability, the history of prior offenses, and the financial condition of the person presenting the claims.
- (3) The total number of acts in which the violation occurred.
- (4) The dollar amount at issue (Medicare Trust Fund dollars or beneficiary out-of-pocket expenses).
- (5) The prior history of the person insofar as its willingness or refusal to comply with requests to correct said violations.
- (6) Any other facts bearing on the nature and seriousness of the person's misconduct.
- (7) Any other matters that justice may require.

(b) *Criteria to be considered.* As a guideline for taking into account the general factors listed in paragraph (a)

of this section, the initiating agency may consider any one or more of the circumstances listed in paragraphs (b)(1) and (b)(2) of this section, as applicable. The respondent, in his or her written response to the notice of intent to exclude (that is, the proposed exclusion), may provide information concerning potential mitigating circumstances.

(1) *Aggravating circumstances.* An aggravating circumstance may be any of the following:

(i) The services or incidents were of several types and occurred over an extended period of time.

(ii) There were numerous services or incidents, or the nature and circumstances indicate a pattern of claims or requests for payment or a pattern of incidents, or whether a specific segment of the population was targeted.

(iii) Whether the person was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for health care items or services at any time before the incident or whether the person presented any claim or made any request for payment that included an item or service subject to a determination under § 402.1.

(iv) There is proof that the person engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to government programs and in connection with the delivery of a health care item or service. The statute of limitations governing civil money penalty proceedings at section 1128A(c)(1) of the Act does not apply to proof of other wrongful conducts as an aggravating circumstance.

(v) The wrongful conduct had an adverse impact on the financial integrity of the Medicare program or its beneficiaries.

(vi) The person was the subject of an adverse action by any other Federal, State, or local government agency or board, and the adverse action is based on the same set of circumstances that serves as a basis for the imposition of the exclusion.

(vii) The noncompliance resulted in a financial loss to the Medicare program of at least \$5,000.

(viii) The number of instances for which full, accurate, and complete disclosure was not made as required, or provided as requested, and the significance of the undisclosed information.

(2) *Mitigating circumstances.* A mitigating circumstance may be any of the following:

(i) All incidents of noncompliance were few in nature and of the same type, occurred within a short period of time, and the total amount claimed or requested for the items or services provided was less than \$1,500.

(ii) The claim(s) or request(s) for payment for the item(s) or service(s) provided by the person were the result of an unintentional and unrecognized error in the person's process for presenting claims or requesting payment, and the person took corrective steps promptly after the error was discovered.

(iii) Previous cooperation with a law enforcement or regulatory entity resulted in convictions, exclusions, investigations, reports for weaknesses, or civil money penalties against other persons.

(iv) Alternative sources of the type of health care items or services furnished by the person are not available to the Medicare population in the person's immediate area.

(v) The person took corrective action promptly upon learning of the noncompliance from the person's employee or contractor, or by the Medicare contractor.

(vi) The person had a documented mental, emotional, or physical condition before or during the commission of the noncompliant act(s) and that condition reduces the person's culpability for the acts in question.

(vii) The completeness and timeliness of refunding to the Medicare Trust Fund or Medicare beneficiaries any inappropriate payments.

(viii) The degree of culpability of the person in failing to provide timely and complete refunds.

(3) *Other matters as justice may require.* Other circumstances of an aggravating or mitigating nature are taken into account if, in the interest of justice,

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those circumstances require either a reduction or increase in the sanction to ensure achievement for the purposes of this subpart.

(4) *Initiating agency authority.* Nothing in this section limits the authority of the initiating agency to settle any issue or case as provided by § 402.17, or to compromise any penalty and assessment as provided by § 402.115.

§ 402.209 Scope and effect of exclusion.

(a) *Scope of exclusion.* Under this title, persons may be excluded from the Medicare, Medicaid, and, where applicable, any other Federal health care programs.

(b) *Effect of exclusion on a person(s).* (1) Unless and until an excluded person is reinstated into the Medicare program, no payment is made by Medicare, Medicaid, and, where applicable, any other Federal health care programs for any item or service furnished by the excluded person or at the direction or request of the excluded person when the person furnishing the item or service knew or had reason to know of the exclusion, on or after the effective date of the exclusion as specified in the notice of exclusion.

(2) An excluded person may not take assignment of a Medicare beneficiary's claim on or after the effective date of the exclusion.

(3) An excluded person that submits, or causes to be submitted, claims for items or services furnished during the exclusion period is subject to civil money penalty liability under section 1128A(a)(1)(D) of the Act, and criminal liability under section 1128B(a)(3) of the Act. In addition, submission of claims, or the causing of claims to be submitted for items or services furnished, ordered, or prescribed, by an excluded person may serve as the basis for denying reinstatement to the Medicare program.

(c) *Exceptions.* (1) If a Medicare beneficiary or other person (including a supplier) submits an otherwise payable claim for items or services furnished by an excluded person, or under the medical direction or on the request of an excluded person after the effective date of the exclusion, CMS pays the first claim submitted by the beneficiary or other person and imme-

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diately notifies the claimant of the exclusion. CMS does not pay a beneficiary or other person (including a supplier) for items or services furnished by, or under, the medical direction of an excluded person more than 15 days after the date on the notice to the beneficiary or other person (including a supplier), or after the effective date of the exclusion, whichever is later.

(2) Notwithstanding the other provisions of this section, payment may be made for certain emergency items or services furnished by an excluded person, or under the medical direction or on the request of an excluded person during the period of exclusion. To be payable, a claim for the emergency items or services must be accompanied by a sworn statement of the person furnishing the items or services, specifying the nature of the emergency and the reason that the items or services were not furnished by a person eligible to furnish or order the items or services. No claim for emergency items or services is payable if those items or services were provided by an excluded person that, through employment, contractual, or under any other arrangement, routinely provides emergency health care items or services.

§ 402.210 Notices.

(a) *Notice of proposed determination to exclude.* When the initiating agency proposes to exclude a person from participation in a Federal health care program in accordance with this part, notice of the proposed determination to exclude must be given in writing, and delivered or sent by certified mail, return receipt requested. The written notice must include, at a minimum—

(1) Reference to the statutory basis for the exclusion.

(2) A description of the claims, requests for payment, or incidents for which the exclusion is proposed.

(3) The reason why those claims, requests for payments, or incidents subject the person to an exclusion.

(4) The length of the proposed exclusion.

(5) A description of the circumstances that were considered when determining the period of exclusion.

(6) Instructions for responding to the notice, including a specific statement

of the person's right to submit documentary evidence and a written response concerning whether the exclusion is warranted, and any related issues such as potential mitigating circumstances. The notice must specify that—

(i) The person has the right to request an opportunity to meet with an official of the initiating agency to make an oral presentation; and

(ii) The request to make an oral presentation must be submitted within 30 days of the receipt of the notice of intent to exclude.

(7) If a person fails, within the time permitted under § 402.212, to exercise the right to respond to the notice of proposed determination to exclude, the initiating agency may initiate actions for the imposition of the exclusion.

(b) *Notice of exclusion.* Once the initiating agency determines that the exclusion is warranted, a written notice of exclusion is sent to the person in the same manner as described in paragraph (a) of this section. The exclusion is effective 20 days from the date of the notice. The written notice must include, at a minimum, the following:

(1) The basis for the exclusion.

(2) The length of the exclusion and, when applicable, the factors considered in setting the length.

(3) The effect of exclusion.

(4) The earliest date on which the initiating agency considers a request for reinstatement.

(5) The requirements and procedures for reinstatement.

(6) The appeal rights available to the excluded person under part 1005 of this title.

(c) *Amendment to the notice of exclusion.* No later than 15 days before the final exhibit exchanges required under § 1005.8 of this title, the initiating agency may amend the notice of exclusion if information becomes available that justifies the imposition of a period of exclusion other than the one proposed in the original written notice.

§ 402.212 Response to notice of proposed determination to exclude.

(a) A person that receives a notice of intent to exclude (that is, the proposed determination) as described in § 402.210, may present to the initiating agency a

written response stating whether the proposed exclusion is warranted, and may present additional supportive documentation. The person must submit this response within 60 days of the receipt of notice. The initiating agency reviews the materials presented and initiates a response to the person regarding the argument presented, and any changes to the determination, if appropriate.

(b) The person is also afforded an opportunity to make an oral presentation to the initiating agency concerning whether the proposed exclusion is warranted and any related matters. The person must submit this request within 30 days of the receipt of notice. Within 15 days of receipt of the person's request, the initiating agency initiates communication with the person to establish a mutually agreed upon time and place for the oral presentation and discussion.

§ 402.214 Appeal of exclusion.

(a) The procedures in part 1005 of this title apply to all appeals of exclusions. References to the Inspector General in that part apply to the initiating agency.

(b) A person excluded under this subpart may file a request for a hearing before an administrative law judge (ALJ) only on the issues of whether—

(1) The basis for the imposition of the exclusion exists; and

(2) The duration of the exclusion is unreasonable.

(c) When the initiating agency imposes an exclusion for a period of 1 year or less, paragraph (b)(2) of this section does not apply.

(d) The excluded person must file a request for a hearing within 60 days from the receipt of notice of exclusion. The effective date of an exclusion is not delayed beyond the date stated in the notice of exclusion simply because a request for a hearing is timely filed (see paragraph (g) of this section).

(e) A timely filed written request for a hearing must include—

(1) A statement as to the specific issues or findings of fact and conclusions of law in the notice of exclusion with which the person disagrees.

(2) Basis for the disagreement.

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(3) The general basis for the defenses that the person intends to assert.

(4) Reasons why the proposed length of exclusion should be modified.

(5) Reasons, if applicable, why the health or safety of Medicare beneficiaries receiving items or services does not warrant the exclusion going into or remaining in effect before the completion of an ALJ proceeding in accordance with part 1005 of this title.

(f) If the excluded person does not file a written request for a hearing as provided in paragraph (d) of this section, the initiating agency notifies the excluded person, by certified mail, return receipt requested, that the exclusion goes into effect or continues in accordance with the notice of exclusion. The excluded person has no right to appeal the exclusion other than as described in this section.

(g) If the excluded person files a written request for a hearing, and asserts in the request that the health or safety of Medicare beneficiaries does not warrant the exclusion going into or remaining in effect before completion of an ALJ hearing, then the initiating agency may make a determination as to whether the exclusion goes into effect or continues pending the outcome of the ALJ hearing.

§ 402.300 Request for reinstatement.

(a) An excluded person may submit a written request for reinstatement to the initiating agency no sooner than 120 days prior to the terminal date of exclusion as specified in the notice of exclusion. The written request for reinstatement must include documentation demonstrating that the person has met the standards set forth in § 402.302. Obtaining or reactivating a Medicare provider number (or equivalent) does not constitute reinstatement.

(b) Upon receipt of a written request for reinstatement, the initiating agency may require the person to furnish additional, specific information, and authorization to obtain information from private health insurers, peer review organizations, and others as necessary to determine whether reinstatement is granted.

(c) Failure to submit a written request for reinstatement or to furnish the required information or authoriza-

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tion results in the continuation of the exclusion, unless the exclusion has been in effect for 5 years. In this case, reinstatement is automatic.

(d) If a period of exclusion is reduced on appeal (regardless of whether further appeal is pending), the excluded person may request and apply for reinstatement within 120 days of the expiration of the reduced exclusion period. A written request for the reinstatement includes the same standards as noted in paragraph (b) of this section.

§ 402.302 Basis for reinstatement.

(a) The initiating agency authorizes reinstatement if it determines that—

(1) The period of exclusion has expired;

(2) There are reasonable assurances that the types of actions that formed the basis for the original exclusion did not recur and will not recur; and

(3) There is no additional basis under title XVIII of the Act that justifies the continuation of the exclusion.

(b) The initiating agency does not authorize reinstatement if it determines that submitting claims or causing claims to be submitted or payments to be made by the Medicare program for items or services furnished, ordered, or prescribed, may serve as a basis for denying reinstatement. This section applies regardless of whether the excluded person has obtained a Medicare provider number (or equivalent), either as an individual or as a member of a group, before being reinstated.

(c) In making a determination regarding reinstatement, the initiating agency considers the following:

(1) Conduct of the excluded person occurring before the date of the notice of the exclusion, if that conduct was not known to the initiating agency at the time of the exclusion;

(2) Conduct of the excluded person after the date of the exclusion;

(3) Whether all fines and all debts due and owing (including overpayments) to any Federal, State, or local government that relate to Medicare, Medicaid, or, where applicable, any Federal, State, or local health care program are paid in full, or satisfactory arrangements are made to fulfill these obligations;

(4) Whether the excluded person complies with, or has made satisfactory arrangements to fulfill, all of the applicable conditions of participation or conditions of coverage under the Medicare statutes and regulations; and

(5) Whether the excluded person has, during the period of exclusion, submitted claims, or caused claims to be submitted or payment to be made by Medicare, Medicaid, and, where applicable, any other Federal health care program, for items or services furnished, ordered, or prescribed, and the conditions under which these actions occurred.

(d) Reinstatement is not effective until the initiating agency grants the request and provides notices under § 402.304. Reinstatement is effective as provided in the notice.

(e) A determination for a denial of reinstatement is not appealable or reviewable except as provided in § 402.306.

(f) An ALJ may not require reinstatement of an excluded person in accordance with this chapter.

§ 402.304 Approval of request for reinstatement.

(a) If the initiating agency grants a request for reinstatement, the initiating agency—

(1) Gives written notice to the excluded person specifying the date of reinstatement; and

(2) Notifies appropriate Federal and State agencies, and, to the extent possible, all others that were originally notified of the exclusion, that the person is reinstated into the Medicare program.

(b) A determination by the initiating agency to reinstate an excluded person has no effect if Medicare, Medicaid, or, where applicable, any other Federal health care program has imposed a longer period of exclusion under its own authorities.

§ 402.306 Denial of request for reinstatement.

(a) If a request for reinstatement is denied, the initiating agency provides written notice to the excluded person. Within 30 days of the date of this notice, the excluded person may submit to the initiating agency:

(1) Documentary evidence and a written argument challenging the reinstatement denial; or

(2) A written request to present written evidence or oral argument to an official of the initiating agency.

(b) If a written request as described in paragraph (a)(2) of this section is received timely by the initiating agency, the initiating agency, within 15 days of receipt of the excluded person's request, initiates communication with the excluded person to establish a time and place for the requested meeting.

(c) After evaluating any additional evidence submitted by the excluded person (or at the end of the 30-day period described in paragraph (a) of this section, if no documentary evidence or written request is submitted), the initiating agency sends written notice to the excluded person either confirming the denial, or approving the reinstatement in the manner set forth in § 402.304. If the initiating agency elects to uphold its denial decision, the written notice also indicates that a subsequent request for reinstatement will not be considered until at least 1 year after the date of the written denial notice.

(d) The decision to deny reinstatement is not subject to administrative review.

§ 402.308 Waivers of exclusions.

(a) *Basis.* Section 1128(c)(3)(B) of the Act specifies that in the case of an exclusion from participation in the Medicare program based upon section 1128(a)(1), (a)(3), or (a)(4) of the Act, the individual may request that CMS present, on his or her behalf, a request to the OIG for a waiver of the exclusion.

(b) *Definitions.* For purposes of this section:

Excluded person has the same meaning as a "person" as defined in § 402.3 who meets for the purposes of this subpart, the definition of the term "exclusion" in § 402.3.

Hardship for purposes of this section means something that negatively affects Medicare beneficiaries and results from the imposition of an exclusion because the excluded person is the sole community physician or sole source of

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.

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AUTHORITY: 42 U.S.C. 1395b–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.

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§ 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 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 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

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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.

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(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

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.

(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.

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(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

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.

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(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.

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(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

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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

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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;

(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-

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.

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§ 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

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

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.

Subparts D—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), (γ), 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

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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 treat-

ment 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.

(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 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.

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- (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.

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

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

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

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

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

(b) *Standard: Program responsibilities.*

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

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

§ 403.734 Condition of participation: Food services.

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

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

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

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

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

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

(4) The RNHCI must offer snacks at bedtime.

§ 403.736 Condition of participation: Discharge planning.

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

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

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

(ii) An assessment of the probability of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the RNHCI.

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

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

(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.

[64 FR 67047, Nov. 30, 1999, as amended at 68 FR 66720, Nov. 28, 2003]

§ 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:

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(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).

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

(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.

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

[64 FR 67047, Nov. 30, 1999, as amended at 68 FR 66720, Nov. 28, 2003]

§ 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) Procedures for the proper storage and disposal of trash.

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

(3) An effective pest control program.

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

(5) 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.

[64 FR 67047, Nov. 30, 1999, as amended at 81 FR 64021, Sept. 16, 2016]

§ 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—

(i) The RNHCI must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4).

(ii) Notwithstanding paragraph (a)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.

(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.

(4) The RNHCI may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

(5) When a sprinkler system is shut down for more than 10 hours the RNHCI must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

(6) Building must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016 the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.

(b) *Exceptions.* (1) In consideration of a recommendation by the State survey agency or Accrediting Organization, or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a RNHCI facility, but only if the waiver will not adversely affect the health and safety of the patients.

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(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) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(ii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(iii) TIA 12-2 to NFPA 101, issued October 30, 2012.

(iv) TIA 12-3 to NFPA 101, issued October 22, 2013.

(v) TIA 12-4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

[64 FR 67047, Nov. 30, 1999, as amended at 68 FR 1385, Jan. 10, 2003; 69 FR 18803, Apr. 9, 2004; 69 FR 49240, Aug. 11, 2004; 70 FR 15237, Mar. 25, 2005; 70 FR 71007, Nov. 25, 2005; 71 FR 55339, Sept. 22, 2006; 81 FR 26896, May 4, 2016]

§ 403.745 Condition of participation: Building safety.

(a) *Standard: Building Safety.* Except as otherwise provided in this section the RNHCI must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).

(b) *Standard: Exceptions.* Chapters 7, 8, 12, and 13 of the adopted Health Care

Facilities Code do not apply to a RNHCI.

(c) *Waiver.* If application of the Health Care Facilities Code required under paragraph (a) of this section would result in unreasonable hardship for the RNHCI, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of individuals.

(d) *Incorporation by reference.* The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(2) [Reserved]

[81 FR 26896, May 4, 2016]

§ 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.

(c) *Standard: Utilization review committee role in RNHCI home services.* In addition to the requirements in paragraphs (a) and (b) of this section, the utilization review committee is responsible for:

- (1) The admission, and at least every 30 days, the continued care review of each patient in the RNHCI home services program.
- (2) Oversight and monitoring of the home services program, including the purchase and utilization of designated durable medical equipment items for beneficiaries in the program.

[64 FR 67047, Nov. 30, 1999, as amended at 69 FR 66419, Nov. 15, 2004]

§ 403.748 Condition of participation: Emergency preparedness.

The Religious Nonmedical Health Care Institution (RNHCI) must comply with all applicable Federal, State, and local emergency preparedness requirements. The RNHCI must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The RNHCI must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do all of the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, persons at-risk; the type of services the RNHCI has the ability to provide in an emergency; and, continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the RNHCI's efforts to contact such officials and, when applicable, of its participation in collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The RNHCI must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to the following:

- (i) Food, water, and supplies.
- (ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered patients in the RNHCI's care during an emergency. If on-duty staff and sheltered patients are relocated during the emergency, the RNHCI must document the specific

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name and location of the receiving facility or other location.

(3) Safe evacuation from the RNHCI, which includes the following:

(i) Consideration of care needs of evacuees.

(ii) Staff responsibilities.

(iii) Transportation.

(iv) Identification of evacuation location(s).

(v) Primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the facility.

(5) A system of care documentation that does the following:

(i) Preserves patient information.

(ii) Protects confidentiality of patient information.

(iii) Secures and maintains the availability of records.

(6) The use of volunteers in an emergency and other emergency staffing strategies to address surge needs during an emergency.

(7) The development of arrangements with other RNHCI and other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of nonmedical services to RNHCI patients.

(8) The role of the RNHCI under a waiver declared by the Secretary, in accordance with section 1135 of Act, in the provision of care at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The RNHCI must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Next of kin, guardian or custodian.

(iv) Other RNHCI.

(v) Volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) RNHCI's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and care documentation for patients under the RNHCI's care, as necessary, with care providers to maintain the continuity of care, based on the written election statement made by the patient or his or her legal representative.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the RNHCI's occupancy, needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The RNHCI must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The RNHCI must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Maintain documentation of all emergency preparedness training.

(iv) Demonstrate staff knowledge of emergency procedures.

(2) *Testing.* The RNHCI must conduct exercises to test the emergency plan. The RNHCI must do the following:

(i) Conduct a paper-based, tabletop exercise at least annually. A tabletop exercise is a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(ii) Analyze the RNHCI's response to and maintain documentation of all tabletop exercises, and emergency events, and revise the RNHCI's emergency plan, as needed.

[81 FR 64021, Sept. 16, 2016]

§ 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).

§ 403.754 Monitoring expenditure level.

(a) *Tracking expenditures.* Starting in FFY 1999 CMS begins monitoring Medicare payments to RNHCI's.

(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 RNHCI's exceeds the trigger level for 3 consecutive FFYs, CMS

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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.

§ 403.764 Basis and purpose of religious nonmedical health care institutions providing home service.

(a) *Basis.* This subpart implements sections 1821, 1861, 1861(e), 1861(m), 1861(y), 1861(ss) and 1861(aaa), 1869 and 1878 of the Act regarding Medicare payment for items and services provided in the home setting furnished to eligible beneficiaries by religious nonmedical health care institutions (RNHCIs).

(b) *Purpose.* The home benefit provides for limited durable medical equipment (DME) items and RNHCI services in the home setting that are fiscally limited to \$700,000 per calendar year, with an expiration date of December 31, 2006, or the date on which the 2006 spending limit is reached.

[69 FR 66419, Nov. 15, 2004]

§ 403.766 Requirements for coverage and payment of RNHCI home services.

(a) Medicare Part A pays for RNHCI home services if the RNHCI provider does the following:

(1) Submit a notice of intent to CMS to exercise the option of providing home service.

(2) Provide RNHCI services to eligible beneficiaries,

(3) Arrange with suppliers to furnish appropriate DME items as required to meet documented eligible beneficiary needs.

(4) Arrange for RNHCI nurse home visits to eligible beneficiaries.

(5) Have a utilization committee that assumes the additional responsibility for the oversight and monitoring of the

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items and RNHCI nursing services provided under the home benefit.

(6) Meet all applicable requirements set forth in subpart G of this part.

(b) To be an eligible beneficiary to RNHCI home services the beneficiary must:

(1) Have an effective election in place.

(2) Be confined to the home, as specified in § 409.42(a) of this chapter.

(3) Have a condition that makes him or her eligible to receive services covered under Medicare home health.

(4) Receive home services and DME items from a RNHCI.

(5) Be responsible for deductible and coinsurance for DME, as specified in § 409.50 of this chapter.

[69 FR 66419, Nov. 15, 2004, as amended at 70 FR 16721, Apr. 1, 2005]

§ 403.768 Excluded services.

In addition to items and services excluded in § 409.49 of this chapter, items and services are also excluded if they are provided by:

(a) A HHA that is not a RNHCI.

(b) A supplier who is not providing RNHCI designated items under arrangement with a RNHCI.

(c) A nurse who is not providing RNHCI home nursing services under arrangement with a RNHCI.

[69 FR 66419, Nov. 15, 2004]

§ 403.770 Payments for home services.

(a) The RNHCI nursing visits are paid at the modified low utilization payment adjusted (LUPA) rate used under the home health prospective payment system at § 484.230 of this chapter.

(b) Appropriate DME items are paid as priced by Medicare, minus the deductible and coinsurance liability of the beneficiary.

[69 FR 66419, Nov. 15, 2004]

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

SOURCE: 68 FR 69915, Dec. 15, 2003, unless otherwise noted.

§ 403.800 Basis and scope.

(a) *Basis.* This subpart is based on section 1860D-31 of the Social Security Act (the Act).

(b) *Scope.* This subpart sets forth the standards and procedures CMS uses to implement the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

§ 403.802 Definitions.

For purposes of this subpart, the following definitions apply:

Affiliated organization means an organization that is a legally separate entity from the endorsed drug card sponsor and meets one of the following conditions:

(1) The organization and the endorsed drug card sponsor are under common control. Common control exists if another entity has the power, directly or indirectly, to significantly influence or direct the actions or policies of the organization and the endorsed drug card sponsor.

(2) The organization is under the control of the endorsed drug card sponsor or the organization controls the endorsed drug card sponsor. Control exists if an entity has the power, directly or indirectly, to significantly influence or direct the actions or policies of another entity.

(3) The organization possesses an ownership or equity interest of 5 percent or more in the endorsed drug card sponsor on both the date on which the endorsed drug card sponsor markets the organization's Part D plan, and the date on which the endorsed drug card sponsor signed its endorsement contract with CMS.

Annual coordinated election period means the period beginning on November 15, 2004 and ending on December 31, 2004, during which a discount card enrollee may elect to disenroll from their current endorsed discount card program and elect enrollment in another endorsed discount card program effective January 1, 2005.

Applicant means the non-governmental, single legal organization or entity doing business in the United States that is applying for Medicare endorsement of its prescription drug discount card program, as described in

its application, to be operated by itself or in coordination with subcontractors.

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

Authorized representative means a person with legal authority to act on behalf of an individual in making decisions related to the individual's health care or the individual's enrollment in, disenrollment from, and access to negotiated prices and transitional assistance under the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

Covered discount card drug means any of the following: a drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act; a biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act; insulin described in section 1927(k)(2)(C) of the Act; the following medical supplies associated with the injection of insulin: syringes, needles, alcohol swabs, and gauze; a vaccine licensed under section 351 of the Public Health Service Act; or any use of a covered discount card drug for a medically accepted indication (as defined in section 1927(k)(6) of the Act). The definition of covered discount card drug excludes the following: agents when used for anorexia, weight loss, or weight gain; agents when used to promote fertility; agents when used for cosmetic purposes or hair growth; agents when used for the symptomatic relief of cough and colds; prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; nonprescription drugs; outpatient drugs for which the manufacturer seeks to require that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee as a condition of sale; barbiturates; and benzodiazepines.

Discount card enrollee or enrollee or card enrollee means an individual described in § 403.810(a) who elects to enroll in a Medicare-endorsed prescription drug discount card program.

Effective date means the date on which an enrollment or disenrollment transaction becomes effective.

Enrollment period means the period beginning on the initial enrollment date and ending on December 31, 2005.

Exclusive card program means an endorsed discount card program that is offered by an exclusive card sponsor.

Exclusive card sponsor means an endorsed sponsor that also operates one or more Medicare managed care plans and limits enrollment in its endorsed discount card program to individuals described in §403.810(a) who are enrollees in one of the Medicare managed care plans it offers.

Family size means one for individuals who are single, and two for individuals who are married.

Federal Employee's Health Benefits Program plan means a plan under chapter 89 of title 5 of the United States Code including the Retired Federal Employee's Health Benefits Program.

Formulary means the list of specific drugs from among covered discount card drugs for which an endorsed sponsor offers negotiated prices to Medicare beneficiaries enrolled in its Medicare-endorsed prescription drug discount card program.

Group enrollment means simultaneous enrollment of all or some of the individuals described in section 403.810(a) who are members of a Medicare managed care plan into the exclusive card program offered by the Medicare managed care organization.

HIPAA means the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. 1320d and section 264 of Public Law 104-191.

Income means the components of an individual's adjusted gross income (AGI), as defined under 26 U.S.C. section 62, and, to the extent not included in the components of AGI, retirement and disability benefits, or, if he or she is married, the sum of such income for the individual and his or her spouse.

Initial enrollment date means the date established by the Secretary on which endorsed sponsors may begin accepting beneficiaries' standard enrollment forms.

Initial enrollment year means the period beginning on the initial enroll-

ment date and ending on December 31, 2004.

I/T/U pharmacy means a pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.

Long-term care facility means a skilled nursing facility, as defined in section 1819(a) of the Act, or nursing facility, as defined in section 1919(a) of the Act.

Long-term care pharmacy means a pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents.

Medicare cost plan means an organization that offers enrollment under a reasonable cost reimbursement contract under section 1876(h) of the Act.

Medicare managed care organization means a Part C organization offering a Part C plan described in section 1851(a)(2)(A) of the Act or a Medicare cost plan.

Medicare managed care plan means a plan described in section 1851(a)(2)(A) of the Act offered by a Part C organization or a Medicare cost plan.

Medicare Prescription Drug Discount Card and Transitional Assistance Program or Medicare Drug Discount Card Program means the program established under section 1860D-31 of the Act.

Medicare-endorsed prescription drug discount card program, or endorsed program, or endorsed discount card program means any prescription drug discount card program that has received Medicare endorsement and whose endorsed sponsor has entered into a contract with CMS.

Medicare-endorsed prescription drug discount card sponsor, or endorsed sponsor, or endorsed discount card sponsor means any applicant that has received endorsement from Medicare and entered into a contract with CMS to operate an approved Medicare-endorsed discount card program.

Negotiated price means the discounted price for a covered discount card drug offered by an endorsed sponsor, including any dispensing fee, which takes

into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations.

Network pharmacy means a licensed pharmacy that is not a mail order pharmacy and that is under contract with an endorsed sponsor to provide negotiated prices to its card enrollees and accept transitional assistance as payment for covered discount card drugs provided to its transitional assistance enrollees.

New Medicare managed care organization means an entity applying for approval to enter into a new contract with CMS to offer a new, coordinated care plan or plans as described in section 1851(a)(2)(A) of the Act under Medicare Part C and an exclusive card program under the Medicare Drug Discount Card Program.

Over-the-counter drug means a non-prescription drug.

Part C organization means an organization offering a Part C plan.

Part C plan means a plan described in section 1859(b)(1) of the Act.

Part D plan has the meaning given the term at § 423.4.

Pharmacy network means the group of network pharmacies under contract with an endorsed sponsor.

Poverty line means the income level defined in section 673(2) of the Community Services Block Grant Act, 42 U.S.C. 9902(2), including any revision required by such section, applicable to the family size involved.

Rural means a five-digit zip code in which the population density is less than 1000 persons per square mile.

Second enrollment year means the period beginning on January 1, 2005 and ending on December 31, 2005.

Solicitation means the application materials identified in the notice CMS publishes in the FEDERAL REGISTER announcing its intention to accept and consider applications from applicants seeking Medicare endorsement for their prescription drug discount card programs.

Special election period means the period beginning the day after the effective date of an individual's disenrollment from an endorsed discount card program for one of the reasons listed in § 403.811(b)(2). The length

of any given election period will be specified by CMS in a form and manner that supports the goals of the Medicare Drug Discount Card Program.

Special endorsed sponsor means an endorsed sponsor who has received special endorsement by CMS.

Special endorsement means an endorsement granted under § 403.816 or § 403.817.

Standard enrollment form means an enrollment form or other approved process for enrolling individuals into an endorsed program that incorporates the standard elements provided by CMS.

Subcontractor means an organization or entity doing business in the United States with which an applicant or endorsed sponsor enters into a contract or other legal arrangement in connection with the operation of a prescription drug discount card program.

Suburban means a five-digit zip code in which the population density is between 1000 and 3000 persons per square mile.

Transition period means the period beginning on January 1, 2006 and ending, for individuals enrolled for coverage under Part D, on the effective date of the individual's coverage, and for individuals not so enrolled, on the last day of the initial Part D open enrollment period.

Transitional assistance means a subsidy that transitional assistance enrollees may apply toward the cost of covered discount card drugs in the manner described in § 403.808(d).

Transitional assistance effective date means the date on which a transitional assistance enrollee can access transitional assistance.

Transitional assistance enrollee means an individual described in § 403.810(b) who has applied for and been determined eligible for transitional assistance and has enrolled in a discount card program.

Urban means a five-digit zip code in which the population density is greater than 3000 persons per square mile.

[68 FR 69915, Dec. 15, 2003, as amended at 70 FR 52022, Sept. 1, 2005]

§ 403.804

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§ 403.804 General rules for solicitation, application and Medicare endorsement period.

(a) *Application.* (1) Except as provided in paragraph (a)(2) of this section, an applicant must submit an application to CMS by the deadline announced in the solicitation to be eligible for Medicare endorsement of its prescription drug discount card program. The applicant must certify that based on best knowledge, information, and belief, the reported information is accurate, complete, truthful, and supportable.

(2) A new Medicare managed care organization may simultaneously apply to offer a new Part C plan or plans and an exclusive card program after the deadline announced in the solicitation. New Medicare managed care organizations seeking endorsement of their prescription drug discount card programs must submit an application to CMS at the time that they submit their Part C applications. New Medicare managed care organizations will be eligible for endorsement provided CMS approves their Part C application, the new Medicare managed care organizations demonstrate to CMS that they meet the criteria under paragraph (b) of this section, and the new Medicare managed care organizations demonstrate that they will meet the requirements of paragraph (e)(2) of this section.

(b) *Eligibility to receive endorsement.* Except as specified in §§ 403.814, 403.816 and 403.817, an applicant will be eligible for endorsement if its application demonstrates to CMS's satisfaction that the applicant meets the requirements of § 403.806(a) and § 403.806(b)(1) and that it would operate its endorsed program in a manner consistent with the requirements of § 403.806(b)(2) and (b)(3) through § 403.806(m). An applicant that submits a complete application that meets all of the requirements of this subpart will be eligible to enter into a contract with CMS to operate a Medicare-endorsed prescription drug discount card program. Following the receipt of its Medicare endorsement, an endorsed sponsor must comply with the requirements of § 403.806(b)(2) and (b)(3) through § 403.806(m) through the end of the transition period.

(c) *Ability to subcontract with other organizations and entities.* (1) An applicant

for endorsement may demonstrate that it meets the requirements of this subpart by combining with subcontractors.

(2) Any subcontracts must be in final form satisfactory to CMS, signed by all applicable parties, and filed with CMS before an endorsed sponsor will be permitted to engage in any enrollment or information and outreach.

(3) Once endorsed, an endorsed sponsor must ensure that its subcontractors comply with all applicable requirements of this subpart.

(d) *Period of endorsement.* An applicant eligible to receive endorsement will be required to sign a contract with CMS agreeing to operate its approved Medicare-endorsed prescription drug discount card program(s) until the end of the transition period.

(e)(1) Except as provided in paragraph (e)(2) of this section, we expect an endorsed sponsor to be ready by June 8, 2004, to initiate enrollment and fully operate its endorsed program in compliance with the requirements of § 403.806(b)(2) and (b)(3) through § 403.806(m).

(2) A new Medicare managed care organization must be ready to initiate enrollment and fully operate its exclusive card program in compliance with the requirements of §§ 403.806(b)(2) and (b)(3) through § 403.806(m) upon approval of its Part C application and application for Medicare endorsement of its prescription drug discount card program.

§ 403.806 Sponsor requirements for eligibility for endorsement.

Except as specified in §§ 403.814, 403.816, and 403.817, an endorsed sponsor must meet the following requirements:

(a) *Applicant experience.* (1) An applicant must be a non-governmental, single legal entity doing business in the United States.

(2) An applicant must have 3 years of private sector experience in the United States in pharmacy benefit management, which is defined to mean—

(i) Adjudicating and processing claims for drugs at the point of sale;

(ii) Negotiating with prescription drug manufacturers and others for discounts, rebates, and/or other price concessions on prescription drugs; and

(iii) Administering and tracking individuals' subsidies or benefits in real time.

(3) A single legal entity which is either the applicant or a subcontractor must, at the time of application for Medicare endorsement, operate a pharmacy benefit program, a prescription drug discount card program, a low-income drug assistance program, or a similar program that serves at least 1 million covered lives.

(b) *Financial stability and business integrity.* (1) An applicant must demonstrate a satisfactory record of the financial stability and business integrity of itself, any subcontractors on whom the applicant relies to satisfy the 3 years experience requirement in paragraph (a)(2) of this section and the 1 million covered lives requirement in paragraph (a)(3) of this section, and any subcontractors engaged by the applicant to perform the following activities: develop the pharmacy network; negotiate with manufacturers or pharmacies for rebates, discounts, or other price concessions; handle eligibility for or enrollment in the endorsed sponsor's endorsed discount card program and/or transitional assistance; and administer transitional assistance.

(2) An endorsed sponsor and any subcontractors described in paragraph (b)(1) of this section must maintain a satisfactory record of financial stability and business integrity during the term of the endorsed program.

(3) Medicare endorsement of a discount card program shall not be construed to express or imply any opinion that an endorsed sponsor or any subcontractor of an endorsed sponsor is in compliance with or not liable under the False Claims Act, anti-kickback statute (section 1128B(b) of the Act), or other legal authorities for any improper billing, claims submission, or related conduct.

(c) *Compliance with applicable law.* An endorsed sponsor must comply with all applicable Federal and State laws, including the Federal anti-kickback statute (section 1128B(b) of the Act).

(d) *Prescription drug offering.* An endorsed sponsor must comply with the following discount, rebate, and formulary requirements:

(1) Offer all of its discount card enrollees negotiated prices on covered discount card drugs, which may be limited to those covered discount card drugs included on the endorsed sponsor's formulary.

(2) If the endorsed sponsor uses a formulary, offer a negotiated price on at least one covered discount card drug in each of the lowest level categories for each of the therapeutic groups representing the drugs most commonly needed by Medicare beneficiaries as determined by CMS. A specific covered discount card drug may not be used to fulfill this requirement for more than one category.

(3) Offer a negotiated price on a generic drug in at least 55 percent of the lowest level categories in each of the therapeutic groups representing the drugs most commonly needed by Medicare beneficiaries as determined by CMS.

(4) In setting negotiated prices under this section, an endorsed sponsor may vary its prices and the drugs included on the formulary by pharmacy contract and enrollee characteristics, such as transitional assistance eligibility status.

(5) Synchronize changes in the list of, and negotiated prices for, covered discount card drugs included in the endorsed sponsor's formulary with formulary and negotiated prices published on a price comparison Web site, as described in paragraph (i)(4)(v) of this section.

(6) Obtain rebates, discounts, or other price concessions from manufacturers on covered discount card drugs and pass a share of such concessions to enrollees through negotiated prices.

(7) Guarantee that network and mail order pharmacies provide the lower of the negotiated price or usual and customary price when a covered discount card drug for a negotiated price is available at the point of sale.

(8) Guarantee that a network pharmacy, at the point of sale, inform a discount card enrollee of any differential between the price of a prescribed drug (if it is a covered discount card drug) and the price of the lowest priced generic covered discount card drug that

is therapeutically equivalent and bio-equivalent and available at such pharmacy. Mail order pharmacies are to provide this information at the time of delivery of the drug.

(9) Except during the week of November 15, 2004 (which coincides with the beginning of the annual coordinated election period), ensure that any increase in the negotiated price for a covered discount card drug does not exceed an amount proportionate to the change in the drug's average wholesale price (AWP), and/or an amount proportionate to the changes in the endorsed sponsor's cost structure, including material changes to any discounts, rebates, or other price concessions the endorsed sponsor receives from a pharmaceutical manufacturer or pharmacy.

(e) *Transitional assistance administration.* An endorsed sponsor must administer transitional assistance funds, including any roll-over funds as described in § 403.808(f), for transitional assistance enrollees, through the following procedures:

(1) Establish accounting procedures to manage the transitional assistance funds for each transitional assistance enrollee.

(2) Ensure that transitional assistance funds are applicable to, and only to, all covered discount card drugs available at the endorsed sponsors' network and mail order pharmacies, regardless of formulary.

(3) Ensure that, at network and mail order pharmacies, transitional assistance funds are applied at the lower of negotiated price (if any) and the pharmacy's usual and customary price.

(4) Ensure that network pharmacies make available to the transitional assistance enrollee, electronically or by telephone, at the point-of-sale of covered discount card drugs, the amount of transitional assistance remaining available to the transitional assistance enrollee. Mail order pharmacies are to make this information available by telephone.

(5) Maintain a toll-free telephone number that discount card enrollees may use to determine their transitional assistance balances.

(6) Enforce coinsurance requirements described in § 403.808(e) and ensure that the portion of the price paid through

coinsurance is not deducted from the total transitional assistance funds available to the discount card enrollee.

(f) *Service area and pharmacy access.* An endorsed sponsor must meet the following requirements for its service area and its pharmacy network:

(1) The service area must cover one or more States.

(2) The endorsed sponsor's discount card program must be available to all eligible individuals residing in each State in the endorsed sponsor's service area and may not be offered to individuals residing outside of the United States.

(3) The endorsed sponsor must have a contracted pharmacy network, consisting of pharmacies other than mail-order pharmacies, sufficient to ensure that for beneficiaries residing in the endorsed sponsor's service area the following requirements are satisfied:

(i) At least 90 percent of Medicare beneficiaries, on average, in urban areas served by the endorsed program, live within 2 miles of a network pharmacy;

(ii) At least 90 percent of Medicare beneficiaries, on average, in suburban areas served by the endorsed program, live within 5 miles of a network pharmacy; and

(iii) At least 70 percent of Medicare beneficiaries, on average, in rural areas served by the endorsed program, live within 15 miles of a network pharmacy.

(4) The endorsed sponsor's pharmacy network may be supplemented by pharmacies offering home delivery via mail-order, provided the requirements of paragraph (f)(3) of this section are met.

(g) *Information and outreach and customer service.* (1) An endorsed sponsor must provide through the Internet and some other tangible medium (such as a mailing) to Medicare beneficiaries information and outreach materials describing its endorsed drug card program, including the following information—

(i) The enrollment fee;

(ii) Negotiated prices offered for covered discount card drugs;

(iii) If offered, discounts on over-the-counter drugs;

(iv) Any other products or services offered under the endorsement; and

(v) Any other information that CMS determines is necessary for a full description of the endorsed discount drug card program.

(2) An endorsed sponsor must include on a Web site the following:

(i) Information regarding when the Web site was last updated; and

(ii) A disclaimer that the information on the Web site may not be current.

(3) An endorsed sponsor must use the following forms which incorporate standard elements provided by CMS:

(i) An enrollment form (except as may be modified for an exclusive card sponsor as discussed in § 403.814(b)(5)(iii)); and

(ii) An eligibility determination notice.

(4) An endorsed sponsor must provide to each enrollee a card that complies with National Council for Prescription Drug Programs standards.

(5) An endorsed sponsor must meet the following requirements for the review and approval of information and outreach materials:

(i) Comply with the Information and Outreach Guidelines published by CMS except as provided in paragraph (g)(5)(vi) of this section.

(ii) Except as provided in paragraph (g)(5)(iii) of this section, not distribute any information and outreach materials until or unless they are approved by CMS.

(iii) If CMS does not disapprove the initial submission of information and outreach materials within 30 days of receipt of these materials, the materials are deemed approved under paragraph (g)(5)(ii) of this section.

(iv) Information and outreach materials may discuss only products or services inside the scope of endorsement, as described in paragraph (h) of this section.

(v) Information and outreach materials include the same kinds of materials described in 42 CFR 422.80(b), as well as the enrollment form, eligibility determination form, and membership card described in paragraphs (g)(3) and (g)(4) of this section, Web site content, and information regarding discounts for over-the-counter drugs.

(vi) All materials related to products and services that are Part D plans

must comply with the requirements specified in § 423.50 of this chapter.

(6) An endorsed sponsor must 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. The endorsed sponsor must inform enrollees that the toll-free telephone number provides information on the amount of remaining transitional assistance, in accordance with paragraph (e)(5) of this section.

(7) An endorsed sponsor must provide a system to reduce the likelihood of medical errors and adverse drug interactions and to improve medication use.

(h) *Products and services inside and outside the scope of the endorsement.* (1) An endorsed sponsor may provide, under the endorsement, only those products and services inside the scope of the endorsement, including conducting enrollment. An endorsed sponsor must ensure that discount card enrollees are not charged any additional fee (other than the enrollment fee allowed under § 403.811(c)) for products or services inside the scope of the endorsement.

(2) Products and services inside the scope of the endorsement are limited to—

(i) Products or services offered for no additional fee, other than the enrollment fee allowed under § 403.811(c), that are directly related to a covered discount card drug; or

(ii) A discounted price for an over-the-counter drug.

(i) *Reporting.* (1) An endorsed sponsor must report to CMS on a periodic basis information on the major features of the endorsed sponsor's programs that correspond to the qualifications for endorsement, including, but not limited to, information concerning—

(i) Savings from pharmacies and manufacturers obtained through rebates, discounts, and other price concessions;

(ii) Savings shared with discount card enrollees by manufacturer, by all retail pharmacies, by all mail order pharmacies, and by all brand name and all generic covered discount card drugs;

(iii) Dispensing fees;

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(iv) Certified (by the chief financial officer) financial accounting records on transitional assistance used by the transitional assistance enrollees in each month;

(v) Participant utilization and spending statements;

(vi) Utilization and spending for selected drugs;

(vii) Performance on customer service metrics such as call center performance;

(viii) Grievance logs; and

(ix) Endorsed sponsor's compliance with the pharmacy network access standards.

(2) An endorsed sponsor must provide notice of, and the rationale for, negotiated price increases, except for increases during the week of November 15, 2004, due to reasons other than changes in average wholesale price (AWP).

(3) An endorsed sponsor must certify that based on best knowledge, information, and belief, the reported information is accurate, complete, truthful, and supportable.

(4) Through a price comparison Web site, an endorsed sponsor must report the following information:

(i) Customer service hours;

(ii) Customer service contact information;

(iii) Endorsed program Web site address;

(iv) Annual enrollment fee; and

(v) Negotiated prices (including any applicable dispensing fee), for every covered discount card drug included in the discount card program's offering.

(5) CMS may require endorsed sponsors to submit, in standard terminology, descriptions of other discount card related services they provide, such as pharmacist services.

(j) *Grievance process.* An endorsed sponsor must establish and maintain a grievance process. This process must be designed to track and appropriately address in a timely manner enrollees' complaints about any aspect of their endorsed program for which the endorsed sponsor is responsible.

(k) *Eligibility, enrollment, and disenrollment.* (1) An endorsed sponsor must make preliminary eligibility determinations in accordance with § 403.810 and conduct enrollment and

disenrollment in accordance with § 403.811.

(1) *Authorized representative.* An endorsed sponsor must treat an individual's authorized representative as the individual, if under applicable law, the authorized representative has the legal authority to act on behalf of the individual with respect to the action at issue.

(m) *Other.* An endorsed sponsor must meet the requirements of §§ 403.812, 403.813, and 403.822 of this subpart.

[68 FR 69915, Dec. 15, 2003, as amended at 70 FR 52023, Sept. 1, 2005]

§ 403.808 Use of transitional assistance funds.

(a) *Individuals determined eligible for transitional assistance in 2004.* Subject to paragraph (d) of this section, an individual who, in calendar year 2004, is determined eligible for transitional assistance under § 403.810(b) is entitled to the following:

(1) \$600 in calendar year 2004; and

(2) \$600 in calendar year 2005.

(b) *Individuals determined eligible for transitional assistance in 2005.* Subject to paragraph (d) of this section, an individual who, in calendar year 2005, is determined eligible for transitional assistance under § 403.810(b) is entitled to one of the following amounts for calendar year 2005:

(1) If the complete application for the individual's transitional assistance eligibility is received on or after January 1, 2005 and before April 1, 2005, \$600.

(2) If the complete application for the individual's transitional assistance eligibility is received on or after April 1, 2005 and before July 1, 2005, \$450.

(3) If the complete application for the individual's transitional assistance eligibility is received on or after July 1, 2005 and before October 1, 2005, \$300.

(4) If the complete application for the individual's transitional assistance eligibility is received on or after October 1, 2005 and on or before December 31, 2005, \$150.

(c) *Payment of enrollment fee.* An individual found eligible for transitional assistance is entitled to have CMS pay the annual enrollment fee to the endorsed sponsor on his or her behalf.

(d) *Conditions on use of transitional assistance.* A transitional assistance enrollee may access the transitional assistance described in paragraphs (a) and (b) of this section only if the following conditions are met:

(1) Except as provided in § 403.814(b)(3)(v), the transitional assistance funds are applied toward the cost of a covered discount card drug obtained under the Medicare Prescription Drug Discount Card and Transitional Assistance Program;

(2) The individual pays a coinsurance amount in accordance with § 403.808(e);

(3) The individual purchases the covered discount card drug on or after the individual's transitional assistance effective date; and

(4) The individual is enrolled in the Medicare Prescription Drug Discount Card and Transitional Assistance Program on the date the individual's claim for the covered discount card drug is adjudicated.

(e) *Coinsurance.* If sufficient transitional assistance funds are available, transitional assistance funds must be expended in accordance with the following:

(1) For beneficiaries with incomes at or below 100 percent of the poverty line, 95 percent of the price of a covered discount card drug must be paid from the available transitional assistance funds.

(2) For beneficiaries with incomes greater than 100 percent but at or below 135 percent of the poverty line, 90 percent of the price of a covered discount card drug must be paid from the available transitional assistance funds.

(f) *Rollover.* An individual with transitional assistance retains access to any balance of transitional assistance not expended in a calendar year during the next calendar year, up to and including the transition period, if the individual—

(1) Remains in his or her current endorsed discount card program;

(2) Elects a new endorsed program in an Annual Coordinated Election Period; or

(3) Is eligible for a Special Election Period under § 403.811(b)(2) and elects a new endorsed discount card program during such Special Election Period.

§ 403.810 Eligibility and reconsiderations.

(a) *Eligibility for an endorsed discount card program.* An individual is eligible to enroll in an endorsed discount card program only if such individual meets the following conditions:

(1) The individual is entitled to benefits, or enrolled, under Medicare Part A or enrolled under Medicare Part B; and

(2) The individual, at the time of applying to enroll in an endorsed discount card program, is not enrolled in a State medical assistance program under Title XIX of the Act or under a waiver pursuant to section 1115 of the Act, under which the individual is entitled to any medical assistance for outpatient prescribed drugs as described in section 1905(a)(12) of the Act, except as allowed in § 403.817(d).

(b) *Eligibility for transitional assistance.* An individual is eligible to receive transitional assistance if, at the time of applying for transitional assistance, the individual meets the following conditions:

(1) The individual meets the conditions in paragraph (a) of this section;

(2) The individual resides in one of the 50 States or the District of Columbia;

(3) The individual's income is not more than 135 percent of the poverty line applicable to the individual's family size;

(4) The individual does not have coverage for covered discount card drugs under one or more of the following sources:

(i) A group health plan or health insurance coverage, as these terms are defined under section 2791 of the Public Health Service Act, other than a Part C plan or a group health plan consisting solely of excepted benefits (such as a Medigap plan) as the term is defined under section 2791 of the Public Health Service Act;

(ii) Coverage provided under Chapter 55 of Title 10, United States Code, including TRICARE; or

(iii) A Federal Employee's Health Benefits Program plan; and

(5) The individual (or the individual's authorized representative) completes a standard enrollment form and signs and dates the form in accordance with § 403.811(a)(4). By signing the form, the

individual (or the individual's authorized representative) certifies, under penalty of perjury, that, to the best of the individual's knowledge, the information he or she provides on the form is accurate.

(c) *Special rule for QMBs, SLMBs and QIs.* An individual is deemed to meet the income requirements in paragraph (b)(3) of this section if the individual is enrolled under Title XIX of the Act as a—

(1) Qualified Medicare Beneficiary (QMB);

(2) Specified Low-Income Medicare Beneficiary (SLMB); or

(3) Qualified Individual (QI).

(d) *Duration of eligibility determinations.* An individual determined eligible for the Medicare Prescription Drug Discount Card and Transitional Assistance Program and, in the case of transitional assistance enrollees, for transitional assistance, shall remain eligible for the Medicare Prescription Drug Discount Card and Transitional Assistance Program and, in the case of transitional assistance enrollees, for transitional assistance for the duration of the individual's enrollment in the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

(e) *Drug card and transitional assistance benefits not treated as benefits under other Federal programs.* Any benefits received under the Medicare Prescription Drug Discount Card and Transitional Assistance Program must not be taken into account in determining an individual's eligibility for, or the amount of benefits under, any other Federal program.

(f) *Verification of eligibility.* (1) CMS will verify eligibility to enroll in an endorsed discount card program or to receive transitional assistance.

(2) If CMS is unable to verify an individual's eligibility or ineligibility for transitional assistance, CMS can require the individual to provide additional income information in a form and manner specified by CMS as one condition of eligibility for transitional assistance.

(g) *Reconsideration.* (1) If an individual is determined ineligible to enroll in an endorsed discount card program under paragraph (a) of this sec-

tion or determined ineligible to receive transitional assistance under paragraph (b) of this section, the individual (or the individual's authorized representative) has a right to request that an independent review entity under contract with CMS reconsider the determination.

(2) Reconsideration requests must be filed within 60 days from date of notice of an ineligibility determination, unless the individual (or the individual's authorized representative) can demonstrate good cause for why the 60-day time frame should be extended.

(3) An individual (or the individual's authorized representative) may submit additional documentary evidence or an explanation about his or her eligibility in writing to the independent review entity, as part of the reconsideration process.

(4) Reconsideration decisions shall be issued by the independent review entity in writing and contain an explanation of the reasoning of the decision.

§ 403.811 Enrollment and disenrollment and associated endorsed sponsor requirements.

(a) *Enrollment process.* (1) An individual (or an individual's authorized representative) applying to enroll in an endorsed discount card program must complete a standard enrollment form or other method allowed by CMS and provide such information to the endorsed discount card program in which the individual wishes to enroll.

(2) An individual electing to join an endorsed discount card program that charges an annual enrollment fee, and who is not applying for transitional assistance, must agree to pay the annual enrollment fee, if any, in a form and manner determined by the endorsed card sponsor.

(3) An individual applying for transitional assistance at the time that they apply for enrollment in an endorsed discount card program may only enroll in the endorsed discount card program at that time if CMS determines that the individual is eligible for transitional assistance. Individuals not found eligible for transitional assistance may enroll in an endorsed discount card program without applying for transitional assistance after being notified of

their ineligibility for transitional assistance.

(4) An individual applying for transitional assistance must complete a standard enrollment form and sign and date the form, certifying, under penalty of perjury or similar sanction for false statements, as to the accuracy of the information provided on the standard enrollment form.

(5) Except as provided in § 403.811(b)(4), an individual who is not currently enrolled in an endorsed card program seeking to enroll in the Medicare Prescription Drug Discount Card and Transitional Assistance Program may do so at any time during the enrollment period.

(6) An individual may not be enrolled in more than one endorsed discount card program at a time.

(7) An individual may enroll in only one endorsed discount card program per year during the enrollment period. An individual enrolling during the initial enrollment year, with the exception of the circumstances under paragraph (b)(2) of this section, may change election for the second enrollment year during the annual coordinated election period. During the second enrollment year, an individual may enroll in only one endorsed discount card program, unless the individual meets the circumstances described in paragraph (b)(2) of this section.

(8) An individual remains enrolled in an endorsed discount card program elected unless—

(i) The individual is disenrolled under paragraph (b) of this section;

(ii) The individual elects a new program during the Annual Coordinated Election Period; or

(iii) The endorsed sponsor terminates its endorsed discount card program, or is terminated.

(9) No new enrollment in an endorsed discount card program or changing election of an endorsed discount card program is allowed during the transition period.

(10) Except as specified in § 403.814(b)(6)(i), an individual may enroll in any endorsed discount card program, and only those endorsed discount card programs, offered in the individual's State of residence.

(11) In order to access negotiated prices or transitional assistance, if applicable, an individual must be enrolled in an endorsed discount card program. Access to negotiated prices begins with the effective date of enrollment and ends with disenrollment. Access to transitional assistance begins with the transitional assistance effective date and ends for claims finalized on the date of disenrollment.

(12) Except as provided in paragraph (b)(5) of this section, an individual may apply for transitional assistance at any time during the enrollment period.

(b) *Disenrollment process.* (1) An enrollee may voluntarily disenroll at any time by notifying (or by having his authorized representative notify) the endorsed sponsor.

(2) An enrolled individual who disenrolls during the enrollment period under the following circumstances is granted a Special Election Period in which the individual may enroll in another endorsed discount card program during the enrollment period:

(i) A move of residence outside the service area of the current program;

(ii) A change in residence to or from a long-term care facility;

(iii) Enrollment in or disenrollment from a Part C plan or Medicare cost plan;

(iv) An individual's current endorsed discount card program is terminated or terminates; or

(v) Other exceptional circumstances, as defined by the Secretary.

(3) Notification in order to effect a disenrollment is not required for an individual disenrolling from a terminating endorsed discount card program or enrolling in or disenrolling from a Medicare managed care plan offering an exclusive card program, or for individuals changing endorsed discount card programs during the Annual Coordinated Election Period.

(4) A drug discount card enrollee who disenrolls from an endorsed discount card program other than for one of the reasons listed in paragraph (b)(2) of this section will no longer be determined eligible for the Medicare Prescription Drug Discount Card and Transitional Assistance Program and, if he or she disenrolls in 2004, must re-apply for the Medicare Prescription

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Drug Discount Card and Transitional Assistance Program should he or she wish to enroll in another endorsed discount card program for the second enrollment year.

(5) An individual receiving transitional assistance who voluntarily disenrolls from an endorsed discount card program other than for one of the reasons listed in paragraph (b)(2) of this section will forfeit any transitional assistance remaining available to the individual on the date of disenrollment, and, if he or she disenrolls in 2004, must re-apply for transitional assistance for 2005 in order to receive transitional assistance in 2005.

(6) A discount card enrollee other than a transitional assistance enrollee may be involuntarily disenrolled from his or her endorsed discount card program for failure to pay the annual enrollment fee on a timely basis.

(7) A discount drug card enrollee other than a transitional assistance enrollee may be charged another annual enrollment fee each time the individual disenrolls from one endorsed discount card program and enrolls in another endorsed discount card program during the calendar year.

(c) *Enrollment fees.* (1) An endorsed sponsor may charge an annual enrollment fee of no more than \$30 to each individual enrolled in its endorsed discount card program.

(2) An endorsed sponsor may not collect an enrollment fee from any individual applying for or receiving transitional assistance.

(3) The annual enrollment fee must not be prorated for portions of the year.

(4) An endorsed sponsor must charge a uniform enrollment fee to every discount card eligible individual, or to the Secretary in the case of individuals receiving transitional assistance, residing in a State.

(5) An endorsed sponsor must refund any enrollment fee collected from a discount card enrollee, or any State that has paid the enrollment fee on behalf of the discount card enrollee, during the calendar year during which the individual is determined eligible to receive transitional assistance.

(6) An endorsed sponsor may not charge an annual enrollment fee during the transition period.

§ 403.812 HIPAA privacy, security, administrative data standards, and national identifiers.

(a) *HIPAA covered entities.* An endorsed sponsor is a HIPAA covered entity and must comply with the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164 as set forth in this section. Those functions of an endorsed sponsor the performance of which are necessary or directly related to the operations of the endorsed discount card program are covered functions for purposes of applying to endorsed sponsors the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164.

(b) *HIPAA privacy requirements.* An endorsed sponsor must comply with the standards, implementation specifications, and requirements in the Standards for Privacy of Individually Identifiable Health Information, 45 CFR parts 160 and 164, subparts A and E, in the same manner as a health plan, except to the extent such requirements are temporarily waived by the Secretary.

(c) *Security requirements—(1) Standard.* An endorsed sponsor must comply with the applicable standards, implementation specifications, and requirements in the HIPAA Security Rule, 45 CFR parts 160 and 164, subparts A and C, in the same manner as other covered entities as of the compliance date of such Rule.

(2) *Attestation.* An applicant in its application shall—

(i) Attest that, as of the initial enrollment date, it will have in place appropriate administrative, technical, and physical safeguards to protect the privacy of protected health information in accordance with 45 CFR 164.530(c); and

(ii) Attest that its information security measures will meet the standards, implementation specifications, and requirements of 45 CFR part 164 subparts A and C as of the initial enrollment date, or, if unable to make this attestation, provide a plan for coming into compliance with these requirements by

the compliance date of the Security Rule set forth in 45 CFR part 164, subpart C.

(d) *Administrative data standards.* An endorsed sponsor must comply with any applicable standards, implementation specifications, and requirements in the Standards for Electronic Transactions under 45 CFR parts 160 and 162 subparts I through R.

(e) *Unique identifiers.* An endorsed sponsor must comply with any applicable standards, implementation specifications, and requirements regarding standard unique identifiers under 45 CFR parts 160 and 162 as of the compliance date of any final rule for standard unique identifiers.

(f) *Applicability of other regulations.* Nothing in this paragraph or in § 403.813 shall be deemed a modification of parts 160, 162 and 164 of title 45, Code of Federal Regulations or otherwise modify the applicability of such regulations to other organizations or covered entities independently subject to the mandates of HIPAA. If an endorsed sponsor is also a health plan, health care provider, or health care clearinghouse, nothing in this paragraph shall impair or otherwise affect the application of HIPAA or parts 160, 162 and 164 of title 45, Code of Federal Regulations to such entity and its performance of those functions which make such entity a health plan, health care provider, or health care clearinghouse.

§ 403.813 Marketing limitations and record retention requirements.

(a) *Marketing limitations.* (1) An endorsed sponsor may only market the following:

(i) Those products and services offered under the endorsed program that are inside the scope of endorsement defined in § 403.806(h) and permitted under § 403.812(b).

(ii) A Part D plan offered by the endorsed sponsor or an affiliated organization of the endorsed sponsor.

(2) An endorsed sponsor may not request that a drug card enrollee or an individual seeking to enroll in its endorsed discount card program authorize the endorsed sponsor to use or disclose individually identifiable health information for purposes of marketing

any product or service not allowed under paragraph (a)(1) of this section.

(3) An endorsed sponsor may not commingle any materials related to the marketing of products and services allowed under paragraph (a)(1) of this section with other marketing materials.

(4) Following termination of an endorsed sponsor's endorsement under §§ 403.820(c), (d) or (e) or termination of the Medicare Drug Discount Card and Transitional Assistance Program, a drug card enrollee's individually identifiable health information collected or maintained by an endorsed sponsor may not be used or disclosed for purposes of marketing any product or service.

(b) *Record retention standard.* (1) An endorsed sponsor must retain records that it creates, collects, or maintains while participating in the Medicare Drug Discount Card and Transitional Assistance Program as part of its operations of an endorsed program for at least 6 years following termination of such program, or, in the event the endorsed sponsor's endorsement is terminated under § 420.820(c), (d), or (e) of this chapter at least 6 years following termination of such endorsement. The Secretary may extend the six-year retention period if an endorsed sponsor's records relate to an ongoing investigation, litigation, or negotiation by the Secretary, the Department of Health and Human Services Office of Inspector General, the Department of Justice, or a State, or such documents otherwise relate to suspicions of fraud and abuse or violations of Federal or State law.

(2) For the period during which an endorsed sponsor retains records as specified in paragraph (b)(1) of this section, an endorsed sponsor must continue to apply security and privacy protections to such records and the information contained therein to the same extent endorsed sponsors are required to do so under §§ 403.812(b) and 403.812(c)(1) prior to termination.

[68 FR 69915, Dec. 15, 2003, as amended at 70 FR 52023, Sept. 1, 2005]

§ 403.814 Special rules concerning Part C organizations and Medicare cost plans and their enrollees.

(a) *General requirements.* (1) A Part C organization and Medicare cost plan may not require enrollment in an endorsed discount card program as a condition for enrollment in its Part C plan or Medicare cost plan.

(2) A Part C organization may subsidize the enrollment fee for an endorsed discount card program, whether operated by the Part C organization or another endorsed sponsor, for individuals described in § 403.810(a), provided that any such benefit is reflected in the Part C organization's Adjusted Community Rate filing.

(b) *Exclusive card sponsors.* (1) A Medicare managed care organization may elect to become an exclusive card sponsor by limiting enrollment in its endorsed discount card program to individuals described in § 403.810(a) who are enrolled in any of its Medicare managed care plans. The Medicare managed care organization must be the applicant for endorsement in order to offer an exclusive card program. Such an election must be made at the time of application for endorsement.

(2) Except as noted in paragraphs (b)(3) and (b)(4) of this section, an exclusive card sponsor must comply with all requirements for endorsed sponsors noted in §§ 403.804 and 403.806.

(3) An exclusive card sponsor is deemed to meet or is exempt from certain specific requirements listed in § 403.806 as follows:

(i) An exclusive card sponsor is deemed to meet the pharmacy network requirement in § 403.806(f)(3) if its pharmacy network is not limited to mail-order pharmacies and is equivalent to the pharmacy network used in its Medicare managed care plan and such pharmacy network has been approved by the Secretary, or, if its Medicare managed care plan does not use a pharmacy network, the Secretary determines that the pharmacy network provides sufficient access to covered discount card drugs at negotiated prices for discount card enrollees under the standard set forth under 42 CFR 422.112 for a Part C organization described in section 1851(a)(2)(A) of the Act, or

under 42 CFR 417.416(e) for a Medicare cost plan.

(ii) An exclusive card sponsor is deemed to meet the service area requirements in § 403.806(f)(1) and (f)(2) if it operates in a service area equivalent to its Medicare managed care plan's service area.

(iii) An exclusive card sponsor is deemed to meet the requirement for financial stability and business integrity in § 403.806(b) through compliance with § 422.400 of this chapter (if a Part C organization described in section 1851(a)(2)(A) of the Act) or compliance with §§ 417.120 and 417.122 of this chapter (if a Medicare cost plan).

(iv) An exclusive card sponsor is deemed to meet the covered lives requirement in § 403.806(a)(3).

(v) An exclusive card sponsor is deemed to meet the requirements of § 403.806(e)(2) if it ensures that transitional assistance funds are applied to, and only to, the cost to transitional assistance enrollees of any covered discount card drugs obtained from a network or mail order pharmacy included in the exclusive card sponsor's pharmacy network, and at the option of the exclusive card sponsor, any covered discount card drug obtained under an outpatient prescription drug benefit offered under the affiliated Medicare managed care plan, including any deductibles, co-payments, coinsurance, and other cost-sharing amounts for which transitional assistance enrollees are responsible under the Medicare managed care plan's outpatient prescription drug benefit.

(4) As the Secretary determines appropriate on a case-by-case basis, any additional requirements discussed in §§ 403.804 and 403.806, except for the requirements in §§ 403.812 and 403.813, may be waived or modified on behalf of an exclusive card sponsor if:

(i) The requirements are duplicative of or conflict with the requirements that a Medicare managed care organization must meet either under Part C or under section 1876 of Title XVIII of the Act; or

(ii) The waiver or modification is necessary to improve coordination between benefits under the Medicare Prescription Drug Discount Card and Transitional Assistance Program and

the benefits either under Part C or under section 1876 of Title XVIII of the Act.

(iii) The applicant seeking to become an exclusive card sponsor requests such waivers or modifications in writing in a manner required by the Secretary.

(5) An exclusive card sponsor may conduct group enrollment according to the following rules:

(i) The exclusive card sponsor must seek CMS verification that its Medicare managed care members are individuals described in § 403.810(a) and enroll such individuals as a group into its exclusive card program.

(ii) The exclusive card sponsor must give all individuals it is enrolling as a group the opportunity to decline enrollment, and the opportunity to apply for transitional assistance.

(iii) The exclusive card sponsor may use a modified version of the standard enrollment form described in § 403.806(g)(3) or other CMS-approved process for group enrollment in its endorsed discount card program.

(6) An individual enrolled in a Medicare managed care plan offered by a Medicare managed care organization offering an exclusive card program to individuals enrolled in such Medicare managed care plan is subject to the following requirements:

(i) The individual may enroll only in the endorsed discount card program offered by his or her Medicare managed care organization.

(ii) If the exclusive card sponsor group elects to group enroll into an exclusive card program members of the Medicare managed plan, the individual must actively decline enrollment to avoid enrollment in the exclusive card program.

(c) *Non-uniformity of Benefits.* Implementation of the Medicare Prescription Drug Discount Card and Transitional Assistance Program, including the provision of transitional assistance and the payment or waiver of any enrollment fee by a Part C organization, will not be taken into account in applying the uniform premium and uniform benefits requirement in sections 1854(c) and 1854(f)(1)(D) of the Act and 42 CFR 422.100(d)(2) and 42 CFR 422.312(b)(2).

§ 403.815 Special rules concerning States.

(a) *Optional State payment of enrollment fee.* (1) A State may enter into payment arrangements with endorsed sponsors to provide payment of some or all of endorsed discount card programs' enrollment fees for some or all of the State's individuals described in § 403.810(a) who are not transitional assistance enrollees, provided the enrollment fees are paid directly by the State to the endorsed sponsor.

(2) Expenditures made by a State for enrollment fees described in paragraph (a)(1) of this section must not be treated as State expenditures for which Federal matching payments are available under titles XIX or XXI of the Act.

(b) *Optional State payment of coinsurance.* (1) A State may enter into payment arrangements with pharmacies to provide payment of some or all of coinsurance amounts described in § 403.808(e) for some or all of the State's transitional assistance enrollees, provided the coinsurance amounts are paid directly by the State to the pharmacy.

(2) Expenditures made by a State for coinsurance described in paragraph (b)(1) of this section must not be treated as State expenditures for which Federal matching payments are available under titles XIX or XXI of the Act.

(c) *Coinsurance for Qualified Medicare Beneficiaries.* For transitional assistance enrollees who are qualified Medicare beneficiaries, any coinsurance liability under § 403.808(e) must not be treated as Medicare cost-sharing coinsurance, under section 1905(p)(3)(B) of the Act, for which a State would otherwise be required to pay.

(d) *State data.* (1) A State must provide data on a monthly basis in an electronic format as determined necessary by the Secretary to effectuate the verification of beneficiary eligibility for the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

(2) Expenditures made by a State in complying with the requirements of paragraph (d)(1) of this section will be treated as State expenditures for which Federal matching payments are available under section 1903(a)(7) of the Act.

§ 403.816 Special rules concerning long-term care and I/T/U pharmacies.

(a) *In general.* (1) An applicant for endorsement may submit an application to become a special endorsed sponsor for long-term care and/or for I/T/U pharmacies.

(2) Of qualified applicants, the Secretary will select at least two of the best-qualified applicants for special endorsement for long-term care and at least two of the best-qualified applicants for special endorsement for I/T/U pharmacies.

(3) Applicants for special endorsement for long-term care must demonstrate in their applications that they meet the requirements in paragraph (b) of this section.

(4) Applicants for special endorsement for I/T/U pharmacies must demonstrate in their applications that they meet the requirements in paragraph (d) of this section.

(b) *Long-term care.* A special endorsed sponsor for long-term care must—

(1) Apply transitional assistance toward the cost of covered discount card drugs obtained by transitional assistance enrollees who reside in long-term care facilities and who receive such prescription drugs through long-term care pharmacies;

(2) Offer contractual arrangements to any long-term care pharmacy seeking reimbursement from transitional assistance for covered discount card drugs provided by such pharmacy to transitional assistance enrollees who reside in long-term care facilities;

(3) Process any submitted claims from network pharmacies and out-of-network long-term care pharmacies that supply covered discount card drugs to transitional assistance enrollees who reside in long-term care facilities, when such enrollees have unspent transitional assistance remaining;

(4) Include special terms and conditions in its contracts with network pharmacies that are long-term care pharmacies to facilitate access to and the administration of transitional assistance to transitional assistance enrollees residing in long-term care facilities, including, but not limited to the following—

(i) Waiving penalties against long-term care pharmacies for submitting late claims to the special endorsed sponsor due to the pharmacy's coordination of benefits activities; and

(ii) Permitting a long-term care pharmacy to limit its services to only transitional assistance enrollees who reside in a long-term care facility served by the long-term care pharmacy.

(5) Except as noted in paragraph (c) of this section, comply with all requirements for endorsed sponsors noted in §§ 403.804 and 403.806.

(c) *Waiver of requirements.* (1) The following requirements will not apply to or will be waived for special endorsed sponsors providing transitional assistance to long-term care residents:

(i) Section 403.806(d) (relating to the prescription drug offering) shall not apply to long-term care pharmacies in the special endorsed sponsor's network; and

(ii) Section 403.806(e)(4) (requiring information about the amount of transitional assistance remaining) shall not apply to long-term care pharmacies in the special endorsed sponsor's network.

(2)(i) As the Secretary determines appropriate on a case-by-case basis, any additional requirements discussed in §§ 403.804 and 403.806, except for the requirements in §§ 403.812 and 403.813, may be waived or modified on behalf of a special endorsed sponsor for long-term care if the waiver or modification is—

(A) Necessary to enable the applicant to either initiate enrollment activities under the special endorsement within 6 months of enactment of section 1860D-31 of the Act, or accommodate the unique needs of long-term care pharmacies; or

(B) Compliance with the requirement(s) in question would be impracticable or inefficient.

(ii) Applicants to become special endorsed sponsors for long-term care must request such waivers or modifications in writing in a manner required by the Secretary.

(d) *I/T/U pharmacies.* A special endorsed sponsor for I/T/U pharmacies must—

(1) Apply transitional assistance toward the cost of covered discount card

drugs obtained by transitional assistance enrollees who are American Indians and Alaska Natives and who receive prescription drugs through I/T/U pharmacies as allowed under paragraph (d)(2) of this section;

(2) Offer contractual arrangements to any I/T/U pharmacy that is in the special endorsed sponsor's service area and seeking reimbursement from transitional assistance for covered discount card drugs provided by such pharmacy to transitional assistance enrollees who are also American Indians/Alaska Natives;

(3) Include special terms and conditions in its contracts with network I/T/U pharmacies to facilitate access to and the administration of transitional assistance for transitional assistance enrollees who are American Indians/Alaska Natives, including, but not limited to the following:

(i) Permitting an I/T/U pharmacy to limit its services to only those transitional assistance enrollees who are American Indians/Alaska Natives, and

(ii) Allowing an I/T/U pharmacy to select which drugs to stock, which may be a more limited set than other retail pharmacies.

(4) Except as noted in paragraph (e) of this section, comply with all requirements for endorsed sponsors noted in §§ 403.804 and 403.806.

(e) *Waiver of requirements.* (1) The following requirements will not apply to or will be waived for special endorsed sponsors providing transitional assistance through I/T/U pharmacies:

(i) Section 403.806(d) (relating to the prescription drug offering) shall not apply to I/T/U pharmacies in the special endorsed sponsor's network; and

(ii) Section 403.806(e)(4) (requiring information about the amount of transitional assistance remaining) shall not apply to I/T/U pharmacies in the special endorsed sponsor's network.

(2)(i) As the Secretary determines appropriate on a case-by-case basis, any additional requirements discussed in §§ 403.804 and 403.806, except for the requirements in §§ 403.812 and 403.813, may be waived or modified on behalf of a special endorsed sponsor for I/T/U pharmacies if the waiver or modification is—

(A) Necessary to enable the applicant to either initiate enrollment activities under the special endorsement within 6 months of enactment of section 1860D-31 of the Act, or accommodate the unique needs of I/T/U pharmacies; or

(B) Compliance with the requirement(s) in question would be impracticable or inefficient.

(ii) Applicants to become special endorsed sponsors for I/T/U pharmacies must request such waivers or modifications in writing in a manner required by the Secretary.

§ 403.817 Special rules concerning the territories.

(a) *In general.* (1) An applicant for endorsement may submit an application to become a special endorsed sponsor for all of the territories.

(2) Of qualified applicants, the Secretary will select at least one of the best-qualified applicants to receive a special endorsement for the territories.

(3) Applicants for special endorsement for the territories must demonstrate in their applications that they meet the requirements in paragraph (b) of this section.

(b) *Requirements—(1) Negotiated prices.* A special endorsed sponsor for residents of the territories must provide access to negotiated prices in the territories.

(2) *Transitional assistance.* Any transitional assistance in the territories must be in accordance with paragraph (e) of this section.

(3) *Requirements, exception.* Except as specified in paragraph (c) of this section, a special endorsed sponsor for the territories must meet the requirements of §§ 403.804 and 403.806.

(c) *Waiver of requirements and alternative requirements.* (1) Section 403.806(d)(8) (requiring information about price differentials) shall not apply to pharmacies located in the territories and which are in the special endorsed sponsor's pharmacy network.

(2) Sections 403.806(f)(2) and (f)(3) will be deemed met if the special endorsed sponsor makes a good faith effort to secure the participation of retail and mail order pharmacies throughout a territory.

(3)(i) As the Secretary determines appropriate on a case-by-case basis, any

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additional requirements discussed in §§ 403.804 and 403.806, except for the requirements in §§ 403.812 and 403.813, may be waived or modified on behalf of a special endorsed sponsor for the territories if—

(A) Such waiver is necessary to enable the applicant to either initiate enrollment activities under the special endorsement within 6 months of enactment of section 1860D-31 of the Act, or accommodate the unique needs of pharmacies in the territories; or

(B) Compliance with the requirement(s) in question would be impracticable or inefficient.

(ii) Applicants to become special endorsed sponsors for the territories must request such waivers or modifications in writing in a manner required by the Secretary.

(d) *Other exceptions.* A special endorsed sponsor for the territories may enroll in its endorsed discount card program Medicaid enrollees with coverage for outpatient prescription drugs, as described in § 403.810(a)(2).

(e) *Transitional assistance provided by Territories.* (1) Transitional assistance in the territories may be administered only according to a plan submitted by a territory and approved by CMS.

(2) Territories choosing to provide transitional assistance must submit a plan to CMS within 90 days of the publication of this regulation. The plan must—

(i) Describe how funds allocated to the territory are to be used to cover the cost of covered discount card drugs obtained by individuals who reside in the territory, who are entitled to benefits under Medicare Part A or enrolled under Medicare Part B, and who have income at or below 135 percent of the poverty line for the contiguous United States; and

(ii) Describe how the territory will ensure that amounts received under the allotment are to be used only to provide covered discount card drugs to those individuals determined eligible for transitional assistance, as described in paragraph (e)(2)(i) of this section, and

(iii) Provide such written assurance for the requirements in paragraph (e)(2)(ii) of this section.

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(3) CMS will review and approve plans submitted and make allotments to territories with approved plans.

(4) CMS may request reports or information to substantiate that the territories have administered the program consistent with the territory's approved transitional assistance plan.

§ 403.820 Sanctions, penalties, and termination.

(a) *Intermediate sanctions.* (1) For the violations listed in paragraph (a)(3) of this section, the following intermediate sanctions may be imposed on any endorsed sponsor:

(i) Suspension of enrollment of Medicare beneficiaries.

(ii) Suspension of information and outreach activities to Medicare beneficiaries.

(2) *Duration of sanctions.* The intermediate sanctions continue in effect until CMS is satisfied that the deficiency on which the determination was based has been corrected and is not likely to recur.

(3) *Sanctionable violations.* The violations for which intermediate sanctions may be imposed are as follows:

(i) Substantial failure to maintain a contracted retail pharmacy network meeting the requirements of § 403.806(f);

(ii) Substantial failure to comply with CMS Information and Outreach Guidelines;

(iii) Substantial failure to provide discount card enrollees with negotiated prices consistent with information reported to CMS for the price comparison Web site and/or reported by the endorsed sponsor;

(iv) Except during the week of November 15, 2004 (which coincides with the beginning of the annual coordinated election period), substantial failure to ensure that the negotiated price for a covered discount card drug does not exceed an amount proportionate to the change in the drug's average wholesale price (AWP), and/or an amount proportionate to changes in the card sponsor's cost structure (including material changes to any discounts, rebates, or other price concessions the sponsor receives from a pharmaceutical manufacturer or pharmacy);

(v) Charging drug card enrollees additional fees beyond a \$30 enrollment fee;

(vi) Charging transitional assistance enrollees any enrollment fee;

(vii) Charging a coinsurance more than 5 percent for those at or below 100 percent of the poverty line, or 10 percent for those above 100 percent but at or below 135 percent of the poverty line;

(viii) Substantial failure to administer properly the transitional assistance funding for transitional assistance enrollees;

(ix) Substantial failure to provide CMS or its designees with requested information related to the endorsed sponsor's endorsed discount card operations; or

(x) Failure to otherwise substantially comply with the requirements of this subpart, including failing to perform the operational requirements of this program or the failure to submit an acceptable plan of correction within the timeframe specified by CMS.

(4) *Written notice of proposed sanctions.*

(i) Prior to imposing sanctions, CMS will send a written notice to the endorsed sponsor stating the nature and basis of the proposed sanction.

(ii) CMS will send a copy of the notice in paragraph (a)(4)(i) of this section to the Office of the Inspector General.

(iii) CMS will allow the endorsed sponsor 15 days from the receipt of notice to provide evidence that it has not committed an act or omission that may fairly be characterized as a basis for sanction.

(iv) Should an endorsed sponsor present evidence described in paragraph (a)(4)(iii) of this section and by the time limit described in that paragraph, a CMS official not involved in the original sanction determination shall review the evidence and provide the endorsed sponsor a concise written decision setting forth the factual and legal basis for the decision that affirms or rescinds the original determination.

(5) *Effective date of sanction.* (i) A sanction is effective 15 days after the date that the endorsed sponsor is notified of the sanction or, if the endorsed sponsor timely seeks reconsideration of that sanction decision, on the date specified in the notice of CMS's reconsideration determination.

(ii) The sanction remains in effect until CMS notifies the endorsed sponsor that CMS is satisfied that the basis for imposing the sanction has been corrected and is not likely to recur.

(b) *Civil monetary penalties*—(1) *OIG penalties.* The Office of the Inspector General (OIG) may impose civil monetary penalties in accordance with 42 CFR parts 1003 and 1005 in addition to, or in place of, sanctions that CMS may impose, as described in paragraph (a) of this section, against an endorsed sponsor whom it determines has knowingly—

(i) Misrepresented or falsified information in information and outreach or comparable material provided to program enrollee or other persons;

(ii) Charged a program enrollee in violation of the terms of the endorsement contract; or

(iii) Used transitional assistance funds in any manner that is inconsistent with the purpose of the transitional assistance program.

(2) *CMS penalties.* If CMS determines that an endorsed sponsor has engaged in conduct that it knows or should know constitutes a violation as described in paragraph (a)(3) of this section, where the failure to perform involves the operational requirements of the program, CMS may impose civil monetary penalties in accordance with 42 CFR parts 1003 and 1005 in addition to, or in place of, the sanctions that CMS may impose, as described in paragraph (a) of this section.

(3) CMS or the OIG may impose civil monetary penalties of no more than \$10,000 for each violation.

(c) *Termination of endorsement by CMS.* (1) CMS may terminate the endorsement contract at any time with notice on the following bases:

(i) Any of the bases for the imposition of intermediate sanctions as stated in paragraph (a)(3) of this section; or

(ii) The endorsed sponsor engaged in false or misleading information and outreach practices; or

(iii) The endorsed sponsor fails to comply with the requirement of § 403.804(e).

(2) CMS shall provide the endorsed sponsor written notice of termination 30 days prior to the CMS-determined effective date of the termination at

which time the endorsed sponsor must do the following:

(i) Provide its discount card enrollees notice of the termination within 10 days of receiving notice from CMS;

(ii) Continue to provide services to its discount card enrollees for 90 days after the discount card enrollees were sent the notice of termination from the endorsed sponsor; and

(iii) Suspend all information and outreach and enrollment activities once enrollees have received the notice of termination.

(3) *Corrective action plan.* Before terminating a contract, CMS shall provide the endorsed sponsor with reasonable opportunity to develop and receive CMS approval of a corrective action plan to correct the deficiencies that are the basis of the proposed termination.

(d) *Termination by endorsed sponsor—*
(1) *Cause for termination.* The endorsed sponsor may terminate its endorsement contract if CMS fails substantially to carry out the terms of the contract.

(2) *Card sponsor notice.* The endorsed sponsor must give advance notice as follows:

(i) To CMS, at least 90 days prior to the intended date of termination. This notice must specify the reasons why the endorsed sponsor is requesting contract termination; and

(ii) To its discount card enrollees, by mail, at least 60 days prior to the termination effective date. This notice must include a written description of alternative endorsed discount card programs that serve the discount card enrollee's address.

(3) *Effective date of termination.* The effective date of the termination is determined by CMS and is at least 90 days after the date CMS receives the endorsed sponsor's notice of intent to terminate.

(e) *Termination by mutual consent.* (1) A contract may be modified or terminated at any time by written mutual consent.

(2) If the contract is terminated by mutual consent, the endorsed sponsor must provide notice to its discount card enrollees as provided in paragraph (d)(2) of this section.

(3) If the contract is modified by mutual consent, the endorsed sponsor must provide notice to its discount card enrollees of any changes that CMS determines are appropriate for notification within timeframes specified by CMS.

(f) *Appeal of contract determinations—*
(1) *Scope.* This section establishes the procedures for reviewing the following contract determinations:

(i) A determination that an applicant is not qualified to enter into a contract with CMS under section 1860D–31 of the Act; and

(i) A determination to terminate a contract with an endorsed sponsor in accordance with paragraph (c) of this section.

(2) *Notice of determination.* When CMS makes an initial contract determination, it gives the endorsed sponsor or applicant written notice specifying—

(i) The reasons for the determination; and

(ii) The endorsed sponsor's or applicant's right to request reconsideration.

(3) *Effect of contract determination.* The contract determination is final and binding unless a timely request for a reconsideration hearing is filed under this section.

(4) *Right to reconsideration.* An endorsed sponsor whose contract is terminated or an applicant denied endorsement may request a hearing for reconsideration of the CMS contract determination.

(5) *Method and place for filing a request.* A request for a reconsideration hearing must be made in writing and filed with the CMS Central Office.

(6) *Time for filing a request.* The request for a reconsideration hearing must be filed within 15 days from the date of the notice of the initial determination.

(7) *Appointment of hearing officer.* CMS shall appoint a hearing officer to conduct the reconsideration. The hearing officer shall be a representative of the Administrator and not otherwise a party to the contract determination.

(8) *Conduct of hearing.* The endorsed sponsor or applicant may be represented by counsel and may present evidence and examine witnesses. A complete recording of the proceedings will be made and transcribed.

(9) *Reconsideration determination.* A reconsideration determination is a new determination that—

(i) Is based on a review of the contract determination, the evidence and findings upon which it was based, and any other written evidence submitted before notice of the reconsidered determination is mailed, including facts relating to the status of the endorsed sponsor subsequent to the contract determination; and

(ii) Affirms, reverses, or modifies the initial contract determination.

(10) *Notice of reconsidered determination.* As soon as practicable after the close of the hearing, the hearing officer issues a written reconsideration determination that contains the following:

(i) Findings with respect to the applicant's qualifications to enter into or an endorsed sponsor's qualifications to remain under a contract with CMS under section 1860D-31 of the Act;

(ii) A statement of the specific reasons for the reconsidered determination.

(11) *Effect of reconsidered determination.* A reconsidered determination is final and binding on the parties and is not subject to judicial review.

(g) *Compliance with HIPAA.* Failure of an endorsed sponsor to comply with HIPAA and/or the standards, implementation specifications, and requirements in 45 CFR parts 160, 162, and 164, as established in §403.812, shall be a violation of HIPAA and may be enforced under sections 1176 and 1177 of the Act.

§ 403.822 Reimbursement of transitional assistance and associated sponsor requirements.

(a) A Transitional Assistance Account is created within the Federal Supplementary Medical Insurance Trust Fund and kept separate from all other funds within that fund.

(b) The Managing Trustee of the Transitional Assistance Account shall pay on a monthly basis from the Account the amounts certified by CMS as necessary to make payments for transitional assistance as allowed in §403.808.

(c) Endorsed sponsors must routinely account to CMS for the transitional assistance provided to the transitional

assistance enrollees for finalized (not pending, or denied) claims up to the allowed balance provided by CMS to the sponsor.

(d) Payment transactions will be audited by the Secretary or his agent.

(e) Federal funding in excess of the amount of the balance included in CMS's system is not permitted.

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

SOURCE: 78 FR 9521, Feb. 8, 2013, unless otherwise noted.

§ 403.900 Purpose and scope.

The regulations in this subpart implement section 1128G of the Act. These regulations apply to applicable manufacturers and applicable group purchasing organizations and describe the requirements and procedures for applicable manufacturers to report payments or other transfers of value provided to covered recipients, as well as for applicable manufacturers and applicable group purchasing organizations to report ownership or investment interests held by physicians or immediate family members of physicians in such entities.

§ 403.902 Definitions.

For purposes of this subpart, the following definitions apply:

Applicable group purchasing organization means an entity that:

- (1) Operates in the United States; and
- (2) Purchases, arranges for or negotiates the purchase of a covered drug, device, biological, or medical supply for a group of individuals or entities, but not solely for use by the entity itself.

Applicable manufacturer means an entity that is operating in the United States and that falls within one of the following categories:

- (1) An entity that is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, biological, or medical supply, but not if such covered drug, device, biological or medical supply is solely for use by or within the

entity itself or by the entity's own patients. This definition does not include distributors or wholesalers (including, but not limited to, repackagers, relabelers, and kit assemblers) that do not hold title to any covered drug, device, biological or medical supply.

(2) An entity under common ownership with an entity in paragraph (1) of this definition, which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Assistance and support means providing a service or services that are necessary or integral to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological or medical supply.

Charitable contribution includes, but is not limited to, any payment or transfer of value made to an organization with tax-exempt status under the Internal Revenue Code of 1986, which is not provided in exchange for any goods, items or services.

Charity care means services provided by a covered recipient specifically for a patient who is unable to pay for such services or for whom payment would be a significant hardship, where the covered recipient neither receives, nor expects to receive, payment because of the patient's inability to pay.

Clinical investigation means any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug, device, biological or medical supply is administered, dispensed or used.

Common ownership refers to circumstances where the same individual, individuals, entity, or entities directly or indirectly own 5 percent or more total ownership of two entities. This includes, but is not limited to, parent corporations, direct and indirect subsidiaries, and brother or sister corporations.

Covered drug, device, biological, or medical supply means any drug, device, biological, or medical supply for which payment is available under Title XVIII of the Act or under a State plan under

Title XIX or XXI of the Act (or a waiver of such plan), either separately (such as through a fee schedule or formulary) or as part of a bundled payment (for example, under the hospital inpatient prospective payment system or the hospital outpatient prospective payment system) and which is of the type that in the case of a—

(1) Drug or biological, by law, requires a prescription to be dispensed; or

(2) Device (including a medical supply that is a device), by law, requires premarket approval by or premarket notification to the FDA.

Covered recipient means— (1) Any physician, except for a physician who is a bona fide employee of the applicable manufacturer that is reporting the payment; or

(2) A teaching hospital, which is any institution that received a payment under 1886(d)(5)(B), 1886(h), or 1886(s) of the Act during the last calendar year for which such information is available.

Employee means an individual who is considered to be “employed by” or an “employee” of an entity if the individual would be considered to be an employee of the entity under the usual common law rules applicable in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986).

Immediate family member means any of the following:

- (1) Spouse.
- (2) Natural or adoptive parent, child, or sibling.
- (3) Stepparent, stepchild, stepbrother, or stepsister.
- (4) Father-, mother-, daughter-, son-, brother-, or sister-in-law.
- (5) Grandparent or grandchild.
- (6) Spouse of a grandparent or grandchild.

Indirect payments or other transfers of value refer to payments or other transfers of value made by an applicable manufacturer (or an applicable group purchasing organization) to a covered recipient (or a physician owner or investor) through a third party, where the applicable manufacturer (or applicable group purchasing organization)

requires, instructs, directs, or otherwise causes the third party to provide the payment or transfer of value, in whole or in part, to a covered recipient(s) (or a physician owner or investor).

Know, knowing, or knowingly—(1) Means that a person, with respect to information—

(i) Has actual knowledge of the information;

(ii) Acts in deliberate ignorance of the truth or falsity of the information; or

(iii) Acts in reckless disregard of the truth or falsity of the information; and

(2) Requires no proof of a specific intent to defraud.

NPPES stands for the National Plan & Provider Enumeration System.

Operating in the United States means that an entity—

(1) Has a physical location within the United States or in a territory, possession, or commonwealth of the United States; or

(2) Otherwise conducts activities within the United States or in a territory, possession, or commonwealth of the United States, either directly or through a legally-authorized agent.

Ownership or investment interest—(1) Includes, but is not limited to the following:

(i) Stock, stock option(s) (other than those received as compensation, until they are exercised).

(ii) Partnership share(s);

(iii) Limited liability company membership(s).

(iv) Loans, bonds, or other financial instruments that are secured with an entity's property or revenue or a portion of that property or revenue.

(2) May be direct or indirect and through debt, equity or other means.

(3) *Exceptions.* The following are not ownership or investment interests for the purposes of this section:

(i) An ownership or investment interest in a publicly traded security or mutual fund, as described in section 1877(c) of the Act.

(ii) An interest in an applicable manufacturer or applicable group purchasing organization that arises from a retirement plan offered by the applicable manufacturer or applicable group purchasing organization to the physi-

cian (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that applicable manufacturer or applicable group purchasing organization.

(iii) Stock options and convertible securities received as compensation, until the stock options are exercised or the convertible securities are converted to equity.

(iv) An unsecured loan subordinated to a credit facility.

(v) An ownership or investment interest if an applicable manufacturer or applicable group purchasing organization did not know, as defined in this section, about such ownership or investment interest.

Payment or other transfer of value means a transfer of anything of value.

Physician has the same meaning given that term in section 1861(r) of the Act.

Related to a covered drug, device, biological, or medical supply means that a payment or other transfer of value is made in reference to or in connection with one or more covered drugs, devices, biologicals, or medical supplies.

Research includes a systematic investigation designed to develop or contribute to generalizable knowledge relating broadly to public health, including behavioral and social-sciences research. This term encompasses basic and applied research and product development.

Third party means another individual or entity, regardless of whether such individual or entity is operating in the United States.

[78 FR 9521, Feb. 8, 2013, as amended at 79 FR 68000, Nov. 13, 2014]

§ 403.904 Reports of payments or other transfers of value to covered recipients.

(a) *General rule.* (1) Direct and indirect payments or other transfers of value provided by an applicable manufacturer to a covered recipient during the preceding calendar year, and direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer on behalf of a covered recipient during the preceding calendar year, must be reported by the

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applicable manufacturer to CMS on an annual basis.

(2) For CY 2013, only payments or other transfers of value made on or after August 1, 2013 must be reported to CMS.

(b) *Limitations.* Certain limitations on reporting apply in the following circumstances:

(1) Applicable manufacturers for whom total (gross) revenues from covered drugs, devices, biologicals, or medical supplies constituted less than 10 percent of total (gross) revenue during the fiscal year preceding the reporting year are only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals or medical supplies.

(2) Applicable manufacturers under paragraph (2) of the definition in § 403.902 are only required to report payments or other transfers of value that are related to a covered drug, device, biological, or medical supply for which they provided assistance or support to an applicable manufacturer under paragraph (1) of the definition.

(3) Applicable manufacturers under either paragraph (1) or (2) of the definition in § 403.902 that have separate operating divisions that do not manufacture any covered drugs, devices, biologicals, or medical supplies (for example, animal health divisions) are only required to report payments to covered recipients related to the activities of these separate divisions if those payments or other transfers of value are related to a covered drug, device, biological, or medical supply. This includes reporting of payments or other transfers of value that are related to covered drugs, devices, biologicals, or medical supplies made by applicable manufacturers to covered recipients through these operating divisions.

(4) Applicable manufacturers that do not manufacture a covered drug, device, biological, or medical supply except when under a written agreement to manufacture the covered drug, device, biological, or medical supply for another entity, do not hold the FDA approval, licensure, or clearance for the covered drug, device, biological, or medical supply, and are not involved in

the sale, marketing, or distribution of the product, are only required to report payments or other transfers of value that are related to one or more covered drugs, devices, biologicals, or medical supplies.

(c) *Required information to report.* A report must contain all of the following information for each payment or other transfer of value:

(1) *Name of the covered recipient.* For physician covered recipients, the name must be as listed in the National Plan & Provider Enumeration System (if applicable) and include first and last name, middle initial, and suffix (for all that apply).

(2) *Address of the covered recipient.* Primary business address of the covered recipient, including all the following:

- (i) Street address.
- (ii) Suite or office number (if applicable).
- (iii) City.
- (iv) State.
- (v) ZIP code.

(3) *Identifiers for physician covered recipients.* In the case of a covered recipient who is a physician, the following identifiers:

- (i) The specialty.
- (ii) National Provider Identifier (if applicable and as listed in the NPPES). If a National Provider Identifier cannot be identified for a physician, the field may be left blank, indicating that the applicable manufacturer could not find one.
- (iii) State professional license number(s) (for at least one State where the physician maintains a license), and the State(s) in which the license is held.

(4) *Amount of payment or other transfer of value.* A payment or other transfer of value made to a group of covered recipients should be distributed appropriately among the individual covered recipients who requested the payment, on whose behalf the payment was made, or who are intended to benefit from the payment or other transfer of value.

(5) *Date of payment or transfer of value.* The date of each payment or other transfer of value.

(i) For payments or other transfers of value made over multiple dates (rather

than as a lump sum), applicable manufacturers may choose whether to report each payment or other transfer of value as separate line item using the dates the payments or other transfers of value were each made, or as a single line item for the total payment or other transfer of value using the first payment date as the reported date.

(ii) For small payments or other transfers of value reported as a single line item, applicable manufacturers must report the date that the first bundled small payment or other transfer of value was provided to the covered recipient.

(6) *Form of payment or transfer of value.* The form of each payment or other transfer of value, as described in paragraph (d) of this section.

(7) *Nature of payment or transfer of value.* The nature of each payment or other transfer of value, as described in paragraph (e) of this section.

(8) *Related covered drug, device, biological or medical supply.* Report the marketed name of the related covered drugs, devices, biologicals, or medical supplies, and therapeutic area or product category unless the payment or other transfer of value is not related to a particular covered drug, device, biological or medical supply.

(i) For drugs and biologicals, if the marketed name has not yet been selected, applicable manufacturers must indicate the name registered on *clinicaltrials.gov*.

(ii) Applicable manufacturers may report the marketed name and therapeutic area or product category for payments or other transfers of value related to a non-covered drug, device, biological, or medical supply.

(iii) Applicable manufacturers must indicate if the related drug, device, biological, or medical supply is covered or non-covered.

(iv) Applicable manufacturers must indicate if the payment or other transfer of value is not related to any covered or non-covered drug, device, biological or medical supply.

(9) *Eligibility for delayed publication.* Applicable manufacturers must indicate whether a payment or other transfer of value is eligible for delayed publication, as described in § 403.910.

(10) *Payments to third parties.* (i) If the payment or other transfer of value was provided to a third party at the request of or designated on behalf of a covered recipient, the payment or transfer of value must be reported in the name of that covered recipient.

(ii) If the payment or other transfer of value was provided to a third party at the request of or designated on behalf of a covered recipient, the name of the entity that received the payment or other transfer of value (if made to an entity) or indicate “individual” (if made to an individual). If a covered recipient performed a service, but neither accepted the offered payment or other transfer of value nor requested that it be made to a third party, the applicable manufacturer is not required to report the offered payment or other transfer of value unless the applicable manufacturer nonetheless provided it to a third party and designated such payment or other transfer of value as having been provided on behalf of the covered recipient.

(11) *Payments or transfers of value to physician owners or investors.* Must indicate whether the payment or other transfer of value was provided to a physician or the immediate family of the physician who holds an ownership or investment interest (as defined § 403.902) in the applicable manufacturer.

(12) *Additional information or context for payment or transfer of value.* May provide a statement with additional context for the payment or other transfer of value.

(d) *Reporting the form of payment or other transfer of value.* An applicable manufacturer must report each payment or transfer of value, or separable part of that payment or transfer of value, as taking one of the following forms of payment that best describes the form of the payment or other transfer of value, or separable part of that payment or other transfer of value.

- (1) Cash or cash equivalent.
- (2) In-kind items or services.
- (3) Stock.
- (4) Stock option.
- (5) Any other ownership interest.
- (6) Dividend, profit or other return on investment.

(e) *Reporting the nature of the payment or other transfer of value.* (1) *General rule.* The categories describing the nature of a payment or other transfer of value are mutually exclusive for the purposes of reporting under subpart I of this part.

(2) *Rules for categorizing natures of payment.* An applicable manufacturer must categorize each payment or other transfer of value, or separable part of that payment or transfer of value, with one of the categories listed in paragraphs (e)(2)(i) through (xvii) of this section, using the designation that best describes the nature of the payment or other transfer of value, or separable part of that payment or other transfer of value. If a payment or other transfer of value could reasonably be considered as falling within more than one category, the applicable manufacturer should select one category that it deems to most accurately describe the nature of the payment or transfer of value.

- (i) Consulting fee.
- (ii) Compensation for services other than consulting, including serving as faculty or as a speaker at an event other than a continuing education program.
- (iii) Honoraria.
- (iv) Gift.
- (v) Entertainment.
- (vi) Food and beverage.
- (vii) Travel and lodging (including the specified destinations).
- (viii) Education.
- (ix) Research.
- (x) Charitable contribution.
- (xi) Royalty or license.
- (xiii) Current or prospective ownership or investment interest.
- (xiv) Compensation for serving as faculty or as a speaker for an unaccredited and non-certified continuing education program.
- (xv) Compensation for serving as faculty or as a speaker for an accredited or certified continuing education program.
- (xvi) Grant.
- (xvii) Space rental or facility fees (teaching hospital only).

(f) *Special rules for research payments.* All payments or other transfers of value made in connection with an activity that meets the definition of re-

search in this section and that are subject to a written agreement, a research protocol, or both, must be reported under these special rules.

(1) Research-related payments or other transfers of value to covered recipients (either physicians or teaching hospitals), including research-related payments or other transfers of value made indirectly to a covered recipient through a third party, must be reported to CMS separately from other payments or transfers of value, and must include the following information (in lieu of the information required by § 403.904(c)):

(i) Name of the research institution, individual or entity receiving the payment or other transfer of value.

(A) If paid to a physician covered recipient, all of the following must be provided:

(1) The physician's name as listed in the NPDES (if applicable).

(2) National Provider Identifier.

(3) State professional license number(s) (for at least one State where the physician maintains a license) and State(s) in which the license is held.

(4) Specialty.

(5) Primary business address of the physician(s).

(B) If paid to a teaching hospital covered recipient, list the name and primary business address of teaching hospital.

(C) If paid to a non-covered recipient (such as a non-teaching hospital or clinic), list the name and primary business address of the entity.

(ii) Total amount of the research payment, including all research-related costs for activities outlined in a written agreement, research protocol, or both.

(iii) Name of the research study.

(iv) Name(s) of any related covered drugs, devices, biologicals, or medical supplies (subject to the requirements specified in paragraph (c)(8) of this section), for drugs and biologicals, the relevant National Drug Code(s), if any, for devices and medical supplies and report a therapeutic area or product category if a marketed name is not available.

(v) Information about each physician covered recipient principal investigator (if applicable) set forth in paragraph (f)(1)(i)(A) of this section.

(vi) Contextual information for research (optional).

(vii) ClinicalTrials.gov identifier (optional).

(2) For pre-clinical studies (before any human studies have begun), only report the following information:

(i) Research entity name (as required in paragraph (f)(1)(i) of this section).

(ii) Total amount of payment (as required in paragraph (f)(1)(ii) of this section).

(ii) Principal investigator(s) (as required in paragraph (f)(1)(v) of this section).

(g) *Special rules for reporting food and beverage.* (1) When allocating the cost of food and beverage among covered recipients in a group setting where the cost of each individual covered recipient's meal is not separately identifiable, such as a platter provided to physicians in a group practice setting, applicable manufacturers must calculate the value per person by dividing the entire cost of the food or beverage by the total number of individuals who partook in the meal (including both covered recipients and non-covered recipients, such as office staff). The per person value of the meal must be reported as a payment or other transfer of value only for covered recipients who actually partook in the food or beverage.

(2) Applicable manufacturers are not required to report or track buffet meals, snacks, soft drinks, or coffee made generally available to all participants of a large-scale conference or similar large-scale event.

(h) *Exclusions from reporting.* The following are excluded from the reporting requirements specified in this section:

(1) Indirect payments or other transfers of value (as defined in § 403.902), where the applicable manufacturer is unaware of the identity of the covered recipient. An applicable manufacturer is unaware of the identity of a covered recipient if the applicable manufacturer does not know (as defined in § 403.902) the identity of the covered recipient during the reporting year or by the end of the second quarter of the following reporting year.

(2)(i) For CY 2013, payments or other transfers of value less than \$10, unless the aggregate amount transferred to, requested by, or designated on behalf of

the covered recipient exceeds \$100 in a calendar year.

(ii) For CY 2014 and subsequent calendar years, to determine if transfers of value are excluded under this section, the dollar amounts specified in paragraph (h)(2)(i) of this section must be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year. CMS will publish the values for the next reporting year 90 days before the beginning of the reporting year.

(iii) Payments or other transfers of value of less than \$10 in CY 2013 (or less than the amount described in paragraph (h)(2)(i) of this section for CY 2014 and subsequent calendar years) provided at large-scale conferences and similar large-scale events, as well as events open to the public, do not need to be reported nor included for purposes of the \$100 aggregate threshold in CY 2013 (or the aggregate threshold calculated in accordance paragraph (h)(2)(i) of this section for CY 2014 and subsequent calendar years), even if the aggregate total for a covered recipient exceeds the aggregate threshold for the calendar year.

(iv) When reporting payments or other transfers of value under the \$10 threshold for CY 2013 (or under the amount described in paragraph (i)(2)(ii) of this section for CY 2014 and subsequent calendar years) for covered recipients that exceed the aggregate threshold for the reporting year, applicable manufacturers may (but are not required to) report all small payments to a particular covered recipient that fall within the same nature of payment category as a single payment or other transfer of value.

(3) Product samples, including coupons and vouchers that can be used by a patient to obtain samples, which are not intended to be sold and are intended for patient use.

(4) Educational materials and items that directly benefit patients or are intended to be used by or with patients, including the value of an applicable manufacturer's services to educate patients regarding a covered drug, device, biological, or medical supply.

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(5) The loan of a covered device or a device under development, or the provision of a limited quantity of medical supplies for a short-term trial period, not to exceed a loan period of 90 days or a quantity of 90 days of average daily use, to permit evaluation of the device or medical supply by the covered recipient.

(6) Items or services provided under a contractual warranty (including service or maintenance agreements), whether or not the warranty period has expired, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

(7) A transfer of anything of value to a physician covered recipient when the covered recipient is a patient, research subject or participant in data collection for research, and not acting in the professional capacity of a covered recipient.

(8) Discounts, including rebates.

(9) In-kind items used for the provision of charity care.

(10) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund.

(11) In the case of an applicable manufacturer who offers a self-insured plan or directly reimburses for healthcare expenses, payments for the provision of health care to employees and their families.

(12) In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of the licensed non-medical professional.

(13) In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to an administrative proceeding, legal defense, prosecution, or settlement or judgment of a civil or criminal action and arbitration.

(14) A payment or transfer of value to a covered recipient if the payment or transfer of value is made solely in the

context of a personal, non-business-related relationship.

[78 FR 9521, Feb. 8, 2013, as amended at 79 FR 68000, Nov. 13, 2014]

§ 403.906 Reports of physician ownership and investment interests.

(a) *General rule.* (1) Each applicable manufacturer and applicable group purchasing organization must report to CMS on an annual basis all ownership and investment interests in the applicable manufacturer or applicable group purchasing organization that were held by a physician or an immediate family member of a physician during the preceding calendar year.

(2) For CY 2013, only ownership or investment interests held on or after August 1, 2013 must be reported to CMS.

(b) *Identifying information.* Reports on physician ownership and investment interests must include the following identifying information:

(1) Name of the physician (as listed in the National Plan & Provider Enumeration System (if applicable), including first and last name, middle initial, and suffix (for all that apply), and an indication of whether the ownership or investment interest was held by the physician or an immediate family member of the physician.

(2) Primary business address of the physician, including the following:

- (i) Street address.
- (ii) Suite or office number (if applicable).
- (iii) City.
- (iv) State.
- (v) ZIP code.

(3) The following information for the physician (regardless of whether the ownership or investment interest is held by an immediate family member of the physician):

- (i) The specialty.
- (ii) National Provider Identifier (if applicable and as listed in NPPES).
- (iii) State professional license number(s) (for at least one State where the physician maintains a license), and the State(s) in which the license is held.

(4) Dollar amount invested by each physician or immediate family member of the physician.

(5) Value and terms of each ownership or investment interest.

(6) Direct and indirect payments or other transfers of value provided to a physician holding an ownership or investment interest, and direct and indirect payments or other transfers of value provided to a third party at the request of or designated by the applicable manufacturer or applicable group purchasing organization on behalf of a physician owner or investor, must be reported by the applicable manufacturer or applicable group purchasing organization in accordance with the requirements for reporting payments or other transfers of value in § 403.904(c) through (h). The terms “applicable manufacturer and applicable group purchasing organization” must be substituted for “applicable manufacturer,” and “physician owner or investor” must be substituted for “covered recipient” in each place they appear.

[78 FR 9521, Feb. 8, 2013, as amended at 79 FR 68001, Nov. 13, 2014]

§ 403.908 Procedures for electronic submission of reports.

(a) *File format.* Reports required under this subpart must be electronically submitted to CMS by March 31, 2014, and by the 90th day of each subsequent calendar year.

(b) *General rules.* (1) If an applicable manufacturer made no reportable payments or transfers of value in the previous calendar year, nor had any reportable ownership or investment interests held by a physician or a physician’s immediate family member (as defined in § 403.902) during the previous calendar year, the applicable manufacturer is not required to file a report.

(2) If an applicable group purchasing organization had no reportable ownership or investment interests held by a physician or physician’s immediate family member during the previous calendar year, the applicable group purchasing organization is not required to file a report.

(c) *Registration.* (1) Applicable manufacturers that have reportable payments or other transfers of value, ownership or investment interests, or both, are required to report under this subpart and must register with CMS within 90 days of the end of the calendar year for which a report is required.

(2) Applicable group purchasing organizations that have reportable ownership or investment interests are required to report under this subpart and must register with CMS within 90 days of the end of the calendar year for which a report is required.

(3) During registration, applicable manufacturers and applicable group purchasing organizations must name two points of contact with appropriate contact information.

(d) *Other rules.* (1) *Consolidated reports.* (i) An applicable manufacturer under paragraph (1) of the definition that is under common ownership with separate entities that are also applicable manufacturers under paragraph (1) of the definition may, but is not required to, file a consolidated report of all the payments or other transfers of value to covered recipients, and physician ownership or investment interests, for all of the entities.

(ii) An applicable manufacturer under paragraph (1) of the definition of applicable manufacturer and an entity (or entities) under common ownership with the applicable manufacturer under paragraph (2) of the definition of applicable manufacturer may, but are not required to, file a consolidated report of all the payments or other transfers of value to covered recipients, and physician ownership or investment interests.

(iii) If multiple applicable manufacturers (under paragraph (1) or (2) of the definition or both paragraphs of the definition) submit a consolidated report, the report must provide the names of each applicable manufacturer and entity (or entities) under common ownership that the report covers, and the report must identify the specific entity that provided each payment.

(iv) A single payment or other transfer of value reported in a consolidated report must only be reported once by one applicable manufacturer.

(v) The applicable manufacturer submitting a consolidated report on behalf of itself and other applicable manufacturers under common ownership, as permitted under this paragraph, is liable for civil monetary penalties imposed on each of the applicable manufacturers whose reportable payments

or other transfers of value were included in the consolidated report, up to the annual maximum amount specified in § 403.912(c) for each individual applicable manufacturer included in the report.

(2) *Joint ventures.* If a payment or other transfer of value is provided in accordance with a joint venture or other cooperative agreement between two or more applicable manufacturers, the payment or other transfer of value must be reported—

(i) In the name of the applicable manufacturer that actually furnished the payment or other transfer of value to the covered recipient, unless the terms of a written agreement between the applicable manufacturers specifically require otherwise, so long as the agreement requires that all payments or other transfers of value in accordance with the arrangement are reported by one of the applicable manufacturers; and

(ii) Only once by one applicable manufacturer.

(e) *Attestation.* Each report, including any subsequent corrections to a filed report, must include an attestation by the Chief Executive Officer, Chief Financial Officer, Chief Compliance Officer, or other Officer of the applicable manufacturer or applicable group purchasing organization that the information reported is timely, accurate, and complete to the best of his or her knowledge and belief. For applicable manufacturers choosing to submit a consolidated report in accordance with paragraph (d)(1) of this section, the applicable manufacturer submitting the consolidated report must attest on behalf of itself, in addition to each of the other applicable manufacturers included in the consolidated report.

(f) *Assumptions document.* Applicable manufacturers and applicable group purchasing organizations may submit an assumptions document, explaining the reasonable assumptions made and methodologies used when reporting payments or other transfers of value, or ownership or investment interests. The assumptions documents will not be made available to covered recipients, physician owners or investors, or the public.

(g) *45-day review period for review and error correction.* (1) *General rule.* Applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors must have an opportunity to review and submit corrections to the information submitted for a period of not less than 45-days before CMS makes the information available to the public. In no case may this 45-day period for review and submission of corrections prevent the information from being made available to the public.

(2) *Notification.* CMS notifies the applicable manufacturers, applicable group purchasing organizations, covered recipients, and physician owners or investors when the reported information is ready for review.

(i) Applicable manufacturers and applicable group purchasing organizations are notified through the points of contact they identified during registration.

(ii) Physicians and teaching hospitals—

(A) Are notified using an online posting and notifications on CMS's listserves.

(B) May also register with CMS to receive notification about the review processes.

(iii) The 45-day review period begins on the date specified in the online notification.

(3) *Process.* (i) An applicable manufacturer, applicable group purchasing organization, covered recipient or a physician owner or investor may log into a secure Web site to view only the information reported specifically about itself.

(ii) Covered recipients and physician owners or investors are able to review data submitted about them for the previous reporting year.

(iii) If the applicable manufacturer, applicable group purchasing organization, covered recipient, or physician owner or investor agrees with the information reported, the applicable manufacturer, applicable group purchasing organization, covered recipient, or physician owner or investor may electronically certify that the information reported is accurate.

(iv) If a covered recipient or physician owner or investor disagrees with

the information reported, the covered recipient or physician owner or investor can initiate a dispute, which is sent to the appropriate applicable manufacturer or applicable group purchasing organization to be resolved between the parties.

(v) Covered recipients and physician owners or investors may initiate disputes at any time after the 45-day period begins, but before the end of the calendar year, but any changes resulting from disputes initiated outside the 45-day period, may not be made until the next time the data is refreshed.

(4) *Data disputes.* (i) In order to be corrected prior to the publication of the data, applicable manufacturers and applicable group purchasing organizations must notify CMS of resolved disputes and changes to the information submitted by no later than 15 days after the end of the 45-day period (that is, 60 days after the 45-day review period begins).

(ii) Disputes which are not resolved by 15 days after the end of the review and correction period, may still be resolved, but any changes resulting from the disputes may be made until the next time the data is refreshed.

(iii) If the dispute is not resolved by 15 days after the end of the 45-day review and correction period, CMS publicly reports and aggregates the applicable manufacturer's or applicable group purchasing organization's version of the payment or other transfer of value, or ownership or investment interest data, but marks the payment or other transfer of value or ownership or investment interest as disputed.

(h) *Errors or omissions.* (1) If an applicable manufacturer or applicable group purchasing organization discovers an error or omission in its annual report, it must submit corrected information to CMS immediately upon confirmation of the error or omission.

(2) Upon receipt, CMS notifies the affected covered recipient or physician owner or investor that the additional information has been submitted and is available for review. CMS updates the Web site at least once annually with corrected information.

§ 403.910 Delayed publication for payments made under product research or development agreements and clinical investigations.

(a) *General rule.* Certain research payments or other transfers of value made to a covered recipient by an applicable manufacturer under a product research or development agreement may be delayed from publication on the Web site. Publication of a payment or other transfer of value is delayed when made in connection with the following instances:

(1) Research on or development of a new drug, device, biological, or medical supply, or a new application of an existing drug, device, biological, or medical supply.

(2) Clinical investigations regarding a new drug, device, biological, or medical supply.

(b) *Research or development agreement.* The research or development agreement must include a written agreement, a research protocol, or both between the applicable manufacturer and covered recipient.

(c) *Date of publication.* Payments or other transfers of value eligible for delayed publication must be reported to CMS (in the manner required in § 403.904(f)) on the first reporting date following the year in which they occur, but CMS does not publicly post the payment until the first annual publication date after the earlier of the following:

(1) The date of the approval, licensure or clearance of the covered drug, device, biological, or medical supply by FDA.

(2) Four calendar years after the date the payment or other transfer of value was made.

(d) *Notification of delayed publication.* (1) An applicable manufacturer must indicate on its research report to CMS whether a payment or other transfer of value is eligible for a delay in publication. The absence of this indication in the report will result in CMS posting all payments publicly in the first year of public reporting.

(2) An applicable manufacturer must continue to indicate annually in its report that FDA approval, licensure, or clearance of the new drug, device, biological or medical supply to which the

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payment or other transfer of value is related, is pending.

(3) An applicable manufacturer must notify CMS during subsequent annual submissions, if the new drug, device, biological or medical supply, to which the payment is related (or the new application of the existing drug, device, biological, or medical supply), is approved by the FDA.

(4) Failure to notify CMS when FDA approval occurs may be considered failure to report, and the applicable manufacturer may be subject to civil monetary penalties.

(5) If, after 4 years from the date of a payment first appearing in a report to CMS, there is an indication in a report that the payment is subject to delayed reporting, it is reported regardless of the indication.

(e) *Confidentiality.* Information submitted and eligible for delayed publication is considered confidential and will not be subject to disclosure under 5 U.S.C. 552, or any similar Federal, State, or local law, until on or after the date on which the information made available to the public as required in this section.

§ 403.912 Penalties for failure to report.

(a) *Failure to report.* (1) Any applicable manufacturer or applicable group purchasing organization that fails to timely, accurately or completely report the information required in accordance with the rules established under this subpart is subject to a civil monetary penalty of not less than \$1,000, but not more than \$10,000, as adjusted annually under 45 CFR part 102 for each payment or other transfer of value or ownership or investment interest not reported timely, accurately, or completely.

(2) The total amount of civil monetary penalties imposed on each applicable manufacturer or applicable group purchasing organization (regardless of whether the applicable manufacturer was a part of a consolidated report) with respect to failures to report in an annual submission of information will not exceed \$150,000 as adjusted annually under 45 CFR part 102.

(b) *Knowing failure to report.* (1) Any applicable manufacturer or applicable

group purchasing organization that knowingly fails to timely, accurately or completely report the information required in accordance with the rules established under this subpart is subject to a civil monetary penalty of not less than \$10,000, but not more than \$100,000, as adjusted annually under 45 CFR part 102 for each payment or other transfer of value or ownership or investment interest not reported timely, accurately, or completely.

(2) The total amount of civil monetary penalties imposed on each applicable manufacturer or group purchasing organization (regardless of whether the applicable manufacturer was a part of a consolidated report) with respect to knowing failures to report in an annual submission of information will not exceed \$1,000,000 as adjusted annually under 45 CFR part 102.

(c) *Total annual civil monetary penalties.* The amount of civil monetary penalties imposed on each applicable manufacturer or applicable group purchasing organization under paragraphs (a)(1) and (b)(1) of this section are—

(1) Aggregated separately;

(2) Subject to separate aggregate totals under paragraphs (a)(2) and (b)(2) of this section, with a maximum combined annual total of \$1,150,000 as adjusted annually under 45 CFR part 102.

(d) *Determinations regarding the amount of civil monetary penalties.* In determining the amount of the civil monetary penalty, factors to be considered include, but are not limited to, the following:

(1) The length of time the applicable manufacturer or applicable group purchasing organization failed to report, including the length of time the applicable manufacturer or applicable group purchasing organization knew of the payment or other transfer of value, or ownership or investment interest.

(2) Amount of the payment the applicable manufacturer or applicable group purchasing organization failed to report.

(3) Level of culpability.

(4) Nature and amount of information reported in error.

(5) Degree of diligence exercised in correcting information reported in error.

(e) *Record retention and audits.* (1) *Maintenance of records.* (i) Applicable manufacturers and applicable group purchasing organizations must maintain all books, contracts, records, documents, and other evidence sufficient to enable the audit, evaluation, and inspection of the applicable manufacturer's or applicable group purchasing organization's compliance with the requirement to timely, accurately or completely submit information in accordance with the rules established under this subpart.

(ii) The items described in paragraph (e)(1)(i) of this section must be maintained for a period of at least 5 years from the date the payment or other transfer of value, or ownership or investment interest is published publicly on the Web site.

(2) *Audit.* HHS, CMS, OIG or their designees may audit, inspect, investigate and evaluate any books, contracts, records, documents, and other evidence of applicable manufacturers and applicable group purchasing organizations that pertain to their compliance with the requirement to timely, accurately or completely submit information in accordance with the rules established under this subpart.

(3) The requirements in this subpart are in addition to, and do not limit, any other applicable requirements that may obligate applicable manufacturers or applicable group purchasing organizations to retain and allow access to records.

(f) *Use of funds.* Funds collected by the Secretary as a result of the imposition of a civil monetary penalty under this section must be used to carry out the operation of this subpart.

(g) *Notice, hearings, appeals, and collection.* Civil monetary penalties imposed under this section are subject to the provisions set forth in subparts A and B of part 402 of this chapter, including those pertaining to notice, opportunity for a hearing, appeals procedures, and collection of penalties.

[78 FR 9521, Feb. 8, 2013, as amended at 81 FR 61561, Sept. 6, 2016; 82 FR 42749, Sept. 12, 2017]

§ 403.914 Preemption of State laws.

(a) *General rule.* In the case of a payment or other transfer of value provided by an applicable manufacturer to

a covered recipient, this subpart preempts any statute or regulation of a State or political subdivision of a State that requires an applicable manufacturer to disclose or report, in any format, the type of information regarding the payment or other transfer of value required to be reported under this subpart.

(b) *Information collected for public health purposes.* (1) Information required to be reported to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes must still be reported to appropriate Federal, State, or local governmental agencies, regardless of whether the same information is required to be reported under this subpart.

(2) Governmental agencies include, but are not limited to, the following:

(i) Agencies that are charged with preventing or controlling disease, injury, disability.

(ii) Agencies that conduct oversight activities authorized by law, including audits, investigations, inspections, licensure or disciplinary actions, or other activities necessary for oversight of the health care system.

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

SOURCE: 79 FR 68001, Nov. 13, 2014, unless otherwise noted.

§ 403.1100 Purpose and scope.

The regulations in this subpart implement section 1115A of the Act. The intent of that section is to enable CMS to test innovative payment and service delivery models to reduce program expenditures while preserving and/or enhancing the quality of care furnished to individuals under titles XVIII, XIX, and XXI of the Act. The Secretary is also required to conduct an evaluation of each model tested.

§ 403.1105 Definitions.

For purposes of this subpart—
Applicable titles means Titles XVIII, XIX, or XXI of the Act.

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§ 403.1110 Evaluation of models.

(a) *Evaluation.* The Secretary conducts an evaluation of each model tested under section 1115A of the Act. Such evaluation must include an analysis of the following:

(1) The quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary.

(2) The changes in spending under the applicable titles by reason of the model.

(b) *Information.* Any State or other entity participating in the testing of a model under section 1115A of the Act must collect and report such information, including “protected health information” as that term is defined at 45 CFR 160.103, as the Secretary determines is necessary to monitor and evaluate such model. Such data must be produced to the Secretary at the time and in the form and manner specified by the Secretary.