

(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 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 de-

ductible 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 enrollment 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

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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.

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*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 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