

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.

*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.