

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 RNHCIs exceeds the trigger level for 3 consecutive FFYs, CMS 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 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.

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(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 Novem-

ber 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