

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 section 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 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 re-

quirements 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