

benefit coordination under section 1395w-102(b)(4)(D) of this title in a manner similar to the manner in which user fees are imposed under section 1395u(h)(3)(B) of this title, except that the Secretary may retain a portion of such fees to defray the Secretary's costs in carrying out procedures under section 1395w-102(b)(4)(D) of this title.

(B) Application

A user fee may not be imposed under subparagraph (A) with respect to a State Pharmaceutical Assistance Program.

(b) Rx Plan

An Rx plan described in this subsection is any of the following:

(1) Medicaid programs

A State plan under subchapter XIX, including such a plan operating under a waiver under section 1315 of this title, if it meets the requirements of section 1395w-133(b)(2) of this title.

(2) Group health plans

An employer group health plan.

(3) FEHBP

The Federal employees health benefits plan under chapter 89 of title 5.

(4) Military coverage (including TRICARE)

Coverage under chapter 55 of title 10.

(5) Other prescription drug coverage

Such other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of part D eligible individuals as the Secretary may specify.

(c) Relation to other provisions

(1) Use of cost management tools

The requirements of this section shall not impair or prevent a PDP sponsor or MA organization from applying cost management tools (including differential payments) under all methods of operation.

(2) No affect¹ on treatment of certain out-of-pocket expenditures

The requirements of this section shall not affect the application of the procedures established under section 1395w-102(b)(4)(D) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D-24, as added Pub. L. 108-173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2130.)

SUBPART 4—MEDICARE PRESCRIPTION DRUG DISCOUNT CARD AND TRANSITIONAL ASSISTANCE PROGRAM

§ 1395w-141. Medicare prescription drug discount card and transitional assistance program

(a) Establishment of program

(1) In general

The Secretary shall establish a program under this section—

(A) to endorse prescription drug discount card programs that meet the requirements of this section in order to provide access to prescription drug discounts through prescription drug card sponsors for discount card eligible individuals throughout the United States; and

(B) to provide for transitional assistance for transitional assistance eligible individuals enrolled in such endorsed programs.

(2) Period of operation

(A) Implementation deadline

The Secretary shall implement the program under this section so that discount cards and transitional assistance are first available by not later than 6 months after December 8, 2003.

(B) Expediting implementation

The Secretary shall promulgate regulations to carry out the program under this section which may be effective and final immediately on an interim basis as of the date of publication of the interim final regulation. If the Secretary provides for an interim final regulation, the Secretary shall provide for a period of public comments on such regulation after the date of publication. The Secretary may change or revise such regulation after completion of the period of public comment.

(C) Termination and transition

(i) In general

Subject to clause (ii)—

(I) the program under this section shall not apply to covered discount card drugs dispensed after December 31, 2005; and

(II) transitional assistance shall be available after such date to the extent the assistance relates to drugs dispensed on or before such date.

(ii) Transition

In the case of an individual who is enrolled in an endorsed discount card program as of December 31, 2005, during the individual's transition period (if any) under clause (iii), in accordance with transition rules specified by the Secretary—

(I) such endorsed program may continue to apply to covered discount card drugs dispensed to the individual under the program during such transition period;

(II) no annual enrollment fee shall be applicable during the transition period;

(III) during such period the individual may not change the endorsed program plan in which the individual is enrolled; and

(IV) the balance of any transitional assistance remaining on January 1, 2006, shall remain available for drugs dispensed during the individual's transition period.

(iii) Transition period

The transition period under this clause for an individual is the period beginning on January 1, 2006, and ending in the case of an individual who—

¹ So in original. Probably should be "effect".

(I) is enrolled in a prescription drug plan or an MA-PD plan before the last date of the initial enrollment period under section 1395w-101(b)(2)(A) of this title, on the effective date of the individual's coverage under such part; or

(II) is not so enrolled, on the last day of such initial period.

(3) Voluntary nature of program

Nothing in this section shall be construed as requiring a discount card eligible individual to enroll in an endorsed discount card program under this section.

(4) Glossary and definitions of terms

For purposes of this section:

(A) Covered discount card drug

The term “covered discount card drug” has the meaning given the term “covered part D drug” in section 1395w-102(e) of this title.

(B) Discount card eligible individual

The term “discount card eligible individual” is defined in subsection (b)(1)(A).

(C) Endorsed discount card program; endorsed program

The terms “endorsed discount card program” and “endorsed program” mean a prescription drug discount card program that is endorsed (and for which the sponsor has a contract with the Secretary) under this section.

(D) Negotiated price

Negotiated prices are described in subsection (e)(1)(A)(ii).

(E) Prescription drug card sponsor; sponsor

The terms “prescription drug card sponsor” and “sponsor” are defined in subsection (h)(1)(A).

(F) State

The term “State” has the meaning given such term for purposes of subchapter XIX.

(G) Transitional assistance eligible individual

The term “transitional assistance eligible individual” is defined in subsection (b)(2).

(b) Eligibility for discount card and for transitional assistance

For purposes of this section:

(1) Discount card eligible individual

(A) In general

The term “discount card eligible individual” means an individual who—

- (i) is entitled to benefits, or enrolled, under part A or enrolled under part B; and
- (ii) subject to paragraph (4), is not an individual described in subparagraph (B).

(B) Individual described

An individual described in this subparagraph is an individual described in subparagraph (A)(i) who is enrolled under subchapter XIX (or under a waiver under section 1315 of this title of the requirements of such subchapter) and is entitled to any med-

ical assistance for outpatient prescribed drugs described in section 1396d(a)(12) of this title.

(2) Transitional assistance eligible individual

(A) In general

Subject to subparagraph (B), the term “transitional assistance eligible individual” means a discount card eligible individual who resides in one of the 50 States or the District of Columbia and whose income (as determined under subsection (f)(1)(B)) is not more than 135 percent of the poverty line (as defined in section 9902(2) of this title, including any revision required by such section) applicable to the family size involved (as determined under subsection (f)(1)(B)).

(B) Exclusion of individuals with certain prescription drug coverage

Such term does not include an individual who has coverage of, or assistance for, covered discount card drugs under any of the following:

- (i) A group health plan or health insurance coverage (as such terms are defined in section 300gg-91 of this title), other than coverage under a plan under part C and other than coverage consisting only of excepted benefits (as defined in such section).
- (ii) Chapter 55 of title 10 (relating to medical and dental care for members of the uniformed services).
- (iii) A plan under chapter 89 of title 5 (relating to the Federal employees' health benefits program).

(3) Special transitional assistance eligible individual

The term “special transitional assistance eligible individual” means a transitional assistance eligible individual whose income (as determined under subsection (f)(1)(B)) is not more than 100 percent of the poverty line (as defined in section 9902(2) of this title, including any revision required by such section) applicable to the family size involved (as determined under subsection (f)(1)(B)).

(4) Treatment of medicaid medically needy

For purposes of this section, the Secretary shall provide for appropriate rules for the treatment of medically needy individuals described in section 1396a(a)(10)(C) of this title as discount card eligible individuals and as transitional assistance eligible individuals.

(c) Enrollment and enrollment fees

(1) Enrollment process

The Secretary shall establish a process through which a discount card eligible individual is enrolled and disenrolled in an endorsed discount card program under this section consistent with the following:

(A) Continuous open enrollment

Subject to the succeeding provisions of this paragraph and subsection (h)(9), a discount card eligible individual who is not enrolled in an endorsed discount card program and is residing in a State may enroll in any such endorsed program—

- (i) that serves residents of the State; and
- (ii) at any time beginning on the initial enrollment date, specified by the Secretary, and before January 1, 2006.

(B) Use of standard enrollment form

An enrollment in an endorsed program shall only be effected through completion of a standard enrollment form specified by the Secretary. Each sponsor of an endorsed program shall transmit to the Secretary (in a form and manner specified by the Secretary) information on individuals who complete such enrollment forms and, to the extent provided under subsection (f), information regarding certification as a transitional assistance eligible individual.

(C) Enrollment only in one program

(i) In general

Subject to clauses (ii) and (iii), a discount card eligible individual may be enrolled in only one endorsed discount card program under this section.

(ii) Change in endorsed program permitted for 2005

The Secretary shall establish a process, similar to (and coordinated with) the process for annual, coordinated elections under section 1395w-21(e)(3) of this title during 2004, under which an individual enrolled in an endorsed discount card program may change the endorsed program in which the individual is enrolled for 2005.

(iii) Additional exceptions

The Secretary shall permit an individual to change the endorsed discount card program in which the individual is enrolled in the case of an individual who changes residence to be outside the service area of such program and in such other exceptional cases as the Secretary may provide (taking into account the circumstances for special election periods under section 1395w-21(e)(4) of this title). Under the previous sentence, the Secretary may consider a change in residential setting (such as placement in a nursing facility) or enrollment in or disenrollment from a plan under part C through which the individual was enrolled in an endorsed program to be an exceptional circumstance.

(D) Disenrollment

(i) Voluntary

An individual may voluntarily disenroll from an endorsed discount card program at any time. In the case of such a voluntary disenrollment, the individual may not enroll in another endorsed program, except under such exceptional circumstances as the Secretary may recognize under subparagraph (C)(iii) or during the annual coordinated enrollment period provided under subparagraph (C)(ii).

(ii) Involuntary

An individual who is enrolled in an endorsed discount card program and not a transitional assistance eligible individual

may be disenrolled by the sponsor of the program if the individual fails to pay any annual enrollment fee required under the program.

(E) Application to certain enrollees

In the case of a discount card eligible individual who is enrolled in a plan described in section 1395w-21(a)(2)(A) of this title or under a reasonable cost reimbursement contract under section 1395mm(h) of this title that is offered by an organization that also is a prescription discount card sponsor that offers an endorsed discount card program under which the individual may be enrolled and that has made an election to apply the special rules under subsection (h)(9)(B) for such an endorsed program, the individual may only enroll in such an endorsed discount card program offered by that sponsor.

(2) Enrollment fees

(A) In general

Subject to the succeeding provisions of this paragraph, a prescription drug card sponsor may charge an annual enrollment fee for each discount card eligible individual enrolled in an endorsed discount card program offered by such sponsor. The annual enrollment fee for either 2004 or 2005 shall not be prorated for portions of a year. There shall be no annual enrollment fee for a year after 2005.

(B) Amount

No annual enrollment fee charged under subparagraph (A) may exceed \$30.

(C) Uniform enrollment fee

A prescription drug card sponsor shall ensure that the annual enrollment fee (if any) for an endorsed discount card program is the same for all discount card eligible individuals enrolled in the program and residing in the State.

(D) Collection

The annual enrollment fee (if any) charged for enrollment in an endorsed program shall be collected by the sponsor of the program.

(E) Payment of fee for transitional assistance eligible individuals

Under subsection (g)(1)(A), the annual enrollment fee (if any) otherwise charged under this paragraph with respect to a transitional assistance eligible individual shall be paid by the Secretary on behalf of such individual.

(F) Optional payment of fee by State

(i) In general

The Secretary shall establish an arrangement under which a State may provide for payment of some or all of the enrollment fee for some or all enrollees who are not transitional assistance eligible individuals in the State, as specified by the State under the arrangement. Insofar as such a payment arrangement is made with respect to an enrollee, the amount of the enrollment fee shall be paid directly by the State to the sponsor.

(ii) No Federal matching available under medicaid or SCHIP

Expenditures made by a State for enrollment fees described in clause (i) shall not be treated as State expenditures for purposes of Federal matching payments under subchapter XIX or XXI.

(G) Rules in case of changes in program enrollment during a year

The Secretary shall provide special rules in the case of payment of an annual enrollment fee for a discount card eligible individual who changes the endorsed program in which the individual is enrolled during a year.

(3) Issuance of discount card

Each prescription drug card sponsor of an endorsed discount card program shall issue, in a standard format specified by the Secretary, to each discount card eligible individual enrolled in such program a card that establishes proof of enrollment and that can be used in a coordinated manner to identify the sponsor, program, and individual for purposes of the program under this section.

(4) Period of access

In the case of a discount card eligible individual who enrolls in an endorsed program, access to negotiated prices and transitional assistance, if any, under such endorsed program shall take effect on such date as the Secretary shall specify.

(d) Provision of information on enrollment and program features

(1) Secretarial responsibilities

(A) In general

The Secretary shall provide for activities under this subsection to broadly disseminate information to discount card eligible individuals (and prospective eligible individuals) regarding—

- (i) enrollment in endorsed discount card programs; and
- (ii) the features of the program under this section, including the availability of transitional assistance.

(B) Promotion of informed choice

In order to promote informed choice among endorsed prescription drug discount card programs, the Secretary shall provide for the dissemination of information which—

- (i) compares the annual enrollment fee and other features of such programs, which may include comparative prices for covered discount card drugs; and
- (ii) includes educational materials on the variability of discounts on prices of covered discount card drugs under an endorsed program.

The dissemination of information under clause (i) shall, to the extent practicable, be coordinated with the dissemination of educational information on other Medicare options.

(C) Special rule for initial enrollment date under the program

To the extent practicable, the Secretary shall ensure, through the activities de-

scribed in subparagraphs (A) and (B), that discount card eligible individuals are provided with such information at least 30 days prior to the initial enrollment date specified under subsection (c)(1)(A)(ii).

(D) Use of Medicare toll-free number

The Secretary shall provide through the toll-free telephone number 1-800-MEDICARE for the receipt and response to inquiries and complaints concerning the program under this section and endorsed programs.

(2) Prescription drug card sponsor responsibilities

(A) In general

Each prescription drug card sponsor that offers an endorsed discount card program shall make available to discount card eligible individuals (through the Internet and otherwise) information that the Secretary identifies as being necessary to promote informed choice among endorsed discount card programs by such individuals, including information on enrollment fees and negotiated prices for covered discount card drugs charged to such individuals.

(B) Response to enrollee questions

Each sponsor offering an endorsed discount card program shall have a mechanism (including a toll-free telephone number) for providing upon request specific information (such as negotiated prices and the amount of transitional assistance remaining available through the program) to discount card eligible individuals enrolled in the program. The sponsor shall inform transitional assistance eligible individuals enrolled in the program of the availability of such toll-free telephone number to provide information on the amount of available transitional assistance.

(C) Information on balance of transitional assistance available at point-of-sale

Each sponsor offering an endorsed discount card program shall have a mechanism so that information on the amount of transitional assistance remaining under subsection (g)(1)(B) is available (electronically or by telephone) at the point-of-sale of covered discount card drugs.

(3) Public disclosure of pharmaceutical prices for equivalent drugs

(A) In general

A prescription drug card sponsor offering an endorsed discount card program shall provide that each pharmacy that dispenses a covered discount card drug shall inform a discount card eligible individual enrolled in the program of any differential between the price of the drug to the enrollee and the price of the lowest priced generic covered discount card drug under the program that is therapeutically equivalent and bioequivalent and available at such pharmacy.

(B) Timing of notice

(i) In general

Subject to clause (ii), the information under subparagraph (A) shall be provided

at the time of purchase of the drug involved, or, in the case of dispensing by mail order, at the time of delivery of such drug.

(ii) Waiver

The Secretary may waive clause (i) in such circumstances as the Secretary may specify.

(e) Discount card features

(1) Savings to enrollees through negotiated prices

(A) Access to negotiated prices

(i) In general

Each prescription drug card sponsor that offers an endorsed discount card program shall provide each discount card eligible individual enrolled in the program with access to negotiated prices.

(ii) Negotiated prices

For purposes of this section, negotiated prices shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered discount card drugs, and include any dispensing fees for such drugs.

(B) Ensuring pharmacy access

Each prescription drug card sponsor offering an endorsed discount card program shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than solely by mail order) drugs directly to enrollees to ensure convenient access to covered discount card drugs at negotiated prices (consistent with rules established by the Secretary). The Secretary shall establish convenient access rules under this clause that are no less favorable to enrollees than the standards for convenient access to pharmacies included in the statement of work of solicitation (#MDA906-03-R-0002) of the Department of Defense under the TRICARE Retail Pharmacy (TRRx) as of March 13, 2003.

(C) Prohibition on charges for required services

(i) In general

Subject to clause (ii), a prescription drug card sponsor (and any pharmacy contracting with such sponsor for the provision of covered discount card drugs to individuals enrolled in such sponsor's endorsed discount card program) may not charge an enrollee any amount for any items and services required to be provided by the sponsor under this section.

(ii) Construction

Nothing in clause (i) shall be construed to prevent—

(I) the sponsor from charging the annual enrollment fee (except in the case of a transitional assistance eligible individual); and

(II) the pharmacy dispensing the covered discount card drug, from imposing a charge (consistent with the negotiated

price) for the covered discount card drug dispensed, reduced by the amount of any transitional assistance made available.

(D) Inapplicability of medicaid best price rules

The prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under this section shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1396r-8(c)(1)(C) of this title.

(2) Reduction of medication errors and adverse drug interactions

Each endorsed discount card program shall implement a system to reduce the likelihood of medication errors and adverse drug interactions and to improve medication use.

(f) Eligibility procedures for endorsed programs and transitional assistance

(1) Determinations

(A) Procedures

The determination of whether an individual is a discount card eligible individual or a transitional assistance eligible individual or a special transitional assistance eligible individual (as defined in subsection (b)) shall be determined under procedures specified by the Secretary consistent with this subsection.

(B) Income and family size determinations

For purposes of this section, the Secretary shall define the terms "income" and "family size" and shall specify the methods and period for which they are determined. If under such methods income or family size is determined based on the income or family size for prior periods of time, the Secretary shall permit (whether through a process of reconsideration or otherwise) an individual whose income or family size has changed to elect to have eligibility for transitional assistance determined based on income or family size for a more recent period.

(2) Use of self-certification for transitional assistance

(A) In general

Under the procedures specified under paragraph (1)(A) an individual who wishes to be treated as a transitional assistance eligible individual or a special transitional assistance eligible individual under this section (or another qualified person on such individual's behalf) shall certify on the enrollment form under subsection (c)(1)(B) (or similar form specified by the Secretary), through a simplified means specified by the Secretary and under penalty of perjury or similar sanction for false statements, as to the amount of the individual's income, family size, and individual's prescription drug coverage (if any) insofar as they relate to eligibility to be a transitional assistance eligible individual or a special transitional assistance eligible individual. Such certification shall be deemed as consent to verification of respec-

tive eligibility under paragraph (3). A certification under this paragraph may be provided before, on, or after the time of enrollment under an endorsed program.

(B) Treatment of self-certification

The Secretary shall treat a certification under subparagraph (A) that is verified under paragraph (3) as a determination that the individual involved is a transitional assistance eligible individual or special transitional assistance eligible individual (as the case may be) for the entire period of the enrollment of the individual in any endorsed program.

(3) Verification

(A) In general

The Secretary shall establish methods (which may include the use of sampling and the use of information described in subparagraph (B)) to verify eligibility for individuals who seek to enroll in an endorsed program and for individuals who provide a certification under paragraph (2).

(B) Information described

The information described in this subparagraph is as follows:

(i) Medicaid-related information

Information on eligibility under subchapter XIX and provided to the Secretary under arrangements between the Secretary and States in order to verify the eligibility of individuals who seek to enroll in an endorsed program and of individuals who provide certification under paragraph (2).

(ii) Social security information

Financial information made available to the Secretary under arrangements between the Secretary and the Commissioner of Social Security in order to verify the eligibility of individuals who provide such certification.

(iii) Information from Secretary of the Treasury

Financial information made available to the Secretary under section 6103(l)(19) of the Internal Revenue Code of 1986 in order to verify the eligibility of individuals who provide such certification.

(C) Verification in cases of medicaid enrollments

(i) In general

Nothing in this section shall be construed as preventing the Secretary from finding that a discount card eligible individual meets the income requirements under subsection (b)(2)(A) if the individual is within a category of discount card eligible individuals who are enrolled under subchapter XIX (such as qualified medicare beneficiaries (QMBs), specified low-income medicare beneficiaries (SLMBs), and certain qualified individuals (QI-1s)).

(ii) Availability of information for verification purposes

As a condition of provision of Federal financial participation to a State that is one

of the 50 States or the District of Columbia under subchapter XIX, for purposes of carrying out this section, the State shall provide the information it submits to the Secretary relating to such subchapter in a manner specified by the Secretary that permits the Secretary to identify individuals who are described in subsection (b)(1)(B) or are transitional assistance eligible individuals or special transitional assistance eligible individuals.

(4) Reconsideration

(A) In general

The Secretary shall establish a process under which a discount card eligible individual, who is determined through the certification and verification methods under paragraphs (2) and (3) not to be a transitional assistance eligible individual or a special transitional assistance eligible individual, may request a reconsideration of the determination.

(B) Contract authority

The Secretary may enter into a contract to perform the reconsiderations requested under subparagraph (A).

(C) Communication of results

Under the process under subparagraph (A) the results of such reconsideration shall be communicated to the individual and the prescription drug card sponsor involved.

(g) Transitional assistance

(1) Provision of transitional assistance

An individual who is a transitional assistance eligible individual (as determined under this section) and who is enrolled with an endorsed program is entitled—

(A) to have payment made of any annual enrollment fee charged under subsection (c)(2) for enrollment under the program; and

(B) to have payment made, up to the amount specified in paragraph (2), under such endorsed program of 90 percent (or 95 percent in the case of a special transitional assistance eligible individual) of the costs incurred for covered discount card drugs obtained through the program taking into account the negotiated price (if any) for the drug under the program.

(2) Limitation on dollar amount

(A) In general

Subject to subparagraph (B), the amount specified in this paragraph for a transitional assistance eligible individual—

(i) for costs incurred during 2004, is \$600;

or

(ii) for costs incurred during 2005, is—

(I) \$600, plus

(II) except as provided in subparagraph (E), the amount by which the amount available under this paragraph for 2004 for that individual exceeds the amount of payment made under paragraph (1)(B) for that individual for costs incurred during 2004.

(B) Proration

(i) In general

In the case of an individual not described in clause (ii) with respect to a year, the

Secretary may prorate the amount specified in subparagraph (A) for the balance of the year involved in a manner specified by the Secretary.

(ii) Individual described

An individual described in this clause is a transitional assistance eligible individual who—

(I) with respect to 2004, enrolls in an endorsed program, and provides a certification under subsection (f)(2), before the initial implementation date of the program under this section; and

(II) with respect to 2005, is enrolled in an endorsed program, and has provided such a certification, before February 1, 2005.

(C) Accounting for available balances in cases of changes in program enrollment

In the case of a transitional assistance eligible individual who changes the endorsed discount card program in which the individual is enrolled under this section, the Secretary shall provide a process under which the Secretary provides to the sponsor of the endorsed program in which the individual enrolls information concerning the balance of amounts available on behalf of the individual under this paragraph.

(D) Limitation on use of funds

Pursuant to subsection (a)(2)(C), no assistance shall be provided under paragraph (1)(B) with respect to covered discount card drugs dispensed after December 31, 2005.

(E) No rollover permitted in case of voluntary disenrollment

Except in such exceptional cases as the Secretary may provide, in the case of a transitional assistance eligible individual who voluntarily disenrolls from an endorsed plan, the provisions of subclause (II) of subparagraph (A)(ii) shall not apply.

(3) Payment

The Secretary shall provide a method for the reimbursement of prescription drug card sponsors for assistance provided under this subsection.

(4) Coverage of coinsurance

(A) Waiver permitted by pharmacy

Nothing in this section shall be construed as precluding a pharmacy from reducing or waiving the application of coinsurance imposed under paragraph (1)(B) in accordance with section 1320a-7b(b)(3)(G) of this title.

(B) Optional payment of coinsurance by State

(i) In general

The Secretary shall establish an arrangement under which a State may provide for payment of some or all of the coinsurance under paragraph (1)(B) for some or all enrollees in the State, as specified by the State under the arrangement. Insofar as such a payment arrangement is made with respect to an enrollee, the amount of the coinsurance shall be paid di-

rectly by the State to the pharmacy involved.

(ii) No Federal matching available under medicaid or SCHIP

Expenditures made by a State for coinsurance described in clause (i) shall not be treated as State expenditures for purposes of Federal matching payments under subchapter XIX or XXI.

(iii) Not treated as medicare cost-sharing

Coinsurance described in paragraph (1)(B) shall not be treated as coinsurance under this subchapter for purposes of section 1396d(p)(3)(B) of this title.

(C) Treatment of coinsurance

The amount of any coinsurance imposed under paragraph (1)(B), whether paid or waived under this paragraph, shall not be taken into account in applying the limitation in dollar amount under paragraph (2).

(5) Ensuring access to transitional assistance for qualified residents of long-term care facilities and American Indians

(A) Residents of long-term care facilities

The Secretary shall establish procedures and may waive requirements of this section as necessary to negotiate arrangements with sponsors to provide arrangements with pharmacies that support long-term care facilities in order to ensure access to transitional assistance for transitional assistance eligible individuals who reside in long-term care facilities.

(B) American Indians

The Secretary shall establish procedures and may waive requirements of this section to ensure that, for purposes of providing transitional assistance, pharmacies operated by the Indian Health Service, Indian tribes and tribal organizations, and urban Indian organizations (as defined in section 1603 of title 25) have the opportunity to participate in the pharmacy networks of at least two endorsed programs in each of the 50 States and the District of Columbia where such a pharmacy operates.

(6) No impact on benefits under other programs

The availability of negotiated prices or transitional assistance under this section shall not be treated as benefits or otherwise taken into account in determining an individual's eligibility for, or the amount of benefits under, any other Federal program.

(7) Disregard for purposes of part C

Nonuniformity of benefits resulting from the implementation of this section (including the provision or nonprovision of transitional assistance and the payment or waiver of any enrollment fee under this section) shall not be taken into account in applying section 1395w-24(f) of this title.

(h) Qualification of prescription drug card sponsors and endorsement of discount card programs; beneficiary protections

(1) Prescription drug card sponsor and qualifications

(A) Prescription drug card sponsor and sponsor defined

For purposes of this section, the terms “prescription drug card sponsor” and “sponsor” mean any nongovernmental entity that the Secretary determines to be appropriate to offer an endorsed discount card program under this section, which may include—

- (i) a pharmaceutical benefit management company;
- (ii) a wholesale or retail pharmacy delivery system;
- (iii) an insurer (including an insurer that offers medicare supplemental policies under section 1395ss of this title);
- (iv) an organization offering a plan under part C; or
- (v) any combination of the entities described in clauses (i) through (iv).

(B) Administrative qualifications

Each endorsed discount card program shall be operated directly, or through arrangements with an affiliated organization (or organizations), by one or more entities that have demonstrated experience and expertise in operating such a program or a similar program and that meets such business stability and integrity requirements as the Secretary may specify.

(C) Accounting for transitional assistance

The sponsor of an endorsed discount card program shall have arrangements satisfactory to the Secretary to account for the assistance provided under subsection (g) on behalf of transitional assistance eligible individuals.

(2) Applications for program endorsement

(A) Submission

Each prescription drug card sponsor that seeks endorsement of a prescription drug discount card program under this section shall submit to the Secretary, at such time and in such manner as the Secretary may specify, an application containing such information as the Secretary may require.

(B) Approval; compliance with applicable requirements

The Secretary shall review the application submitted under subparagraph (A) and shall determine whether to endorse the prescription drug discount card program. The Secretary may not endorse such a program unless—

- (i) the program and prescription drug card sponsor offering the program comply with the applicable requirements under this section; and
- (ii) the sponsor has entered into a contract with the Secretary to carry out such requirements.

(C) Termination of endorsement and contracts

An endorsement of an endorsed program and a contract under subparagraph (B) shall

be for the duration of the program under this section (including any transition applicable under subsection (a)(2)(C)(ii)), except that the Secretary may, with notice and for cause (as defined by the Secretary), terminate such endorsement and contract.

(D) Ensuring choice of programs

(i) In general

The Secretary shall ensure that there is available to each discount card eligible individual a choice of at least 2 endorsed programs (each offered by a different sponsor).

(ii) Limitation on number

The Secretary may limit (but not below 2) the number of sponsors in a State that are awarded contracts under this paragraph.

(3) Service area encompassing entire States

Except as provided in paragraph (9), if a prescription drug card sponsor that offers an endorsed program enrolls in the program individuals residing in any part of a State, the sponsor must permit any discount card eligible individual residing in any portion of the State to enroll in the program.

(4) Savings to medicare beneficiaries

Each prescription drug card sponsor that offers an endorsed discount card program shall pass on to discount card eligible individuals enrolled in the program negotiated prices on covered discount card drugs, including discounts negotiated with pharmacies and manufacturers, to the extent disclosed under subsection (i)(1).

(5) Grievance mechanism

Each prescription drug card sponsor shall provide meaningful procedures for hearing and resolving grievances between the sponsor (including any entity or individual through which the sponsor carries out the endorsed discount card program) and enrollees in endorsed discount card programs of the sponsor under this section in a manner similar to that required under section 1395w-22(f) of this title.

(6) Confidentiality of enrollee records

(A) In general

For purposes of the program under this section, the operations of an endorsed program are covered functions and a prescription drug card sponsor is a covered entity for purposes of applying part C of subchapter XI and all regulatory provisions promulgated thereunder, including regulations (relating to privacy) adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d-2 note).¹

(B) Waiver authority

In order to promote participation of sponsors in the program under this section, the Secretary may waive such relevant portions of regulations relating to privacy referred to

¹ See References in Text note below.

in subparagraph (A), for such appropriate, limited period of time, as the Secretary specifies.

(7) Limitation on provision and marketing of products and services

The sponsor of an endorsed discount card program—

(A) may provide under the program—

(i) a product or service only if the product or service is directly related to a covered discount card drug; or

(ii) a discount price for nonprescription drugs; and

(B) may, to the extent otherwise permitted under paragraph (6) (relating to application of HIPAA requirements), market a product or service under the program only if the product or service is directly related to—

(i) a covered discount card drug; or

(ii) a drug described in subparagraph (A)(i) and the marketing consists of information on the discounted price made available for the drug involved.

(8) Additional protections

Each endorsed discount card program shall meet such additional requirements as the Secretary identifies to protect and promote the interest of discount card eligible individuals, including requirements that ensure that discount card eligible individuals enrolled in endorsed discount card programs are not charged more than the lower of the price based on negotiated prices or the usual and customary price.

(9) Special rules for certain organizations

(A) In general

In the case of an organization that is offering a plan under part C or enrollment under a reasonable cost reimbursement contract under section 1395mm(h) of this title that is seeking to be a prescription drug card sponsor under this section, the organization may elect to apply the special rules under subparagraph (B) with respect to enrollees in any plan described in section 1395w-21(a)(2)(A) of this title that it offers or under such contract and an endorsed discount card program it offers, but only if it limits enrollment under such program to individuals enrolled in such plan or under such contract.

(B) Special rules

The special rules under this subparagraph are as follows:

(i) Limitation on enrollment

The sponsor limits enrollment under this section under the endorsed discount card program to discount card eligible individuals who are enrolled in the part C plan involved or under the reasonable cost reimbursement contract involved and is not required nor permitted to enroll other individuals under such program.

(ii) Pharmacy access

Pharmacy access requirements under subsection (e)(1)(B) are deemed to be met if

the access is made available through a pharmacy network (and not only through mail order) and the network used by the sponsor is approved by the Secretary.

(iii) Sponsor requirements

The Secretary may waive the application of such requirements for a sponsor as the Secretary determines to be duplicative or to conflict with a requirement of the organization under part C or section 1395mm of this title (as the case may be) or to be necessary in order to improve coordination of this section with the benefits under such part or section.

(i) Disclosure and oversight

(1) Disclosure

Each prescription drug card sponsor offering an endorsed discount card program shall disclose to the Secretary (in a manner specified by the Secretary) information relating to program performance, use of prescription drugs by discount card eligible individuals enrolled in the program, the extent to which negotiated price concessions described in subsection (e)(1)(A)(ii) made available to the entity by a manufacturer are passed through to enrollees through pharmacies or otherwise, and such other information as the Secretary may specify. The provisions of section 1396r-8(b)(3)(D) of this title shall apply to drug pricing data reported under the previous sentence (other than data in aggregate form).

(2) Oversight; audit and inspection authority

The Secretary shall provide appropriate oversight to ensure compliance of endorsed discount card programs and their sponsors with the requirements of this section. The Secretary shall have the right to audit and inspect any books and records of a prescription discount card sponsor (and of any affiliated organization referred to in subsection (h)(1)(B)) that pertain to the endorsed discount card program under this section, including amounts payable to the sponsor under this section.

(3) Sanctions for abusive practices

The Secretary may implement intermediate sanctions or may revoke the endorsement of a program offered by a sponsor under this section if the Secretary determines that the sponsor or the program no longer meets the applicable requirements of this section or that the sponsor has engaged in false or misleading marketing practices. The Secretary may impose a civil money penalty in an amount not to exceed \$10,000 for conduct that a party knows or should know is a violation of this section. The provisions of section 1320a-7a of this title (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(j) Treatment of territories

(1) In general

The Secretary may waive any provision of this section (including subsection (h)(2)(D)) in

the case of a resident of a State (other than the 50 States and the District of Columbia) insofar as the Secretary determines it is necessary to secure access to negotiated prices for discount card eligible individuals (or, at the option of the Secretary, individuals described in subsection (b)(1)(A)(i)).

(2) Transitional assistance

(A) In general

In the case of a State, other than the 50 States and the District of Columbia, if the State establishes a plan described in subparagraph (B) (for providing transitional assistance with respect to the provision of prescription drugs to some or all individuals residing in the State who are described in subparagraph (B)(i)), the Secretary shall pay to the State for the entire period of the operation of this section an amount equal to the amount allotted to the State under subparagraph (C).

(B) Plan

The plan described in this subparagraph is a plan that—

(i) provides transitional assistance with respect to the provision of covered discount card drugs to some or all individuals who are entitled to benefits under part A or enrolled under part B, who reside in the State, and who have income below 135 percent of the poverty line; and

(ii) assures that amounts received by the State under this paragraph are used only for such assistance.

(C) Allotment limit

The amount described in this subparagraph for a State is equal to \$35,000,000 multiplied by the ratio (as estimated by the Secretary) of—

(i) the number of individuals who are entitled to benefits under part A or enrolled under part B and who reside in the State (as determined by the Secretary as of July 1, 2003), to

(ii) the sum of such numbers for all States to which this paragraph applies.

(D) Continued availability of funds

Amounts made available to a State under this paragraph which are not used under this paragraph shall be added to the amount available to that State for purposes of carrying out section 1396u-5(e) of this title.

(k) Funding

(1) Establishment of Transitional Assistance Account

(A) In general

There is created within the Federal Supplementary Medical Insurance Trust Fund established by section 1395t of this title an account to be known as the “Transitional Assistance Account” (in this subsection referred to as the “Account”).

(B) Funds

The Account shall consist of such gifts and bequests as may be made as provided in section 401(i)(1) of this title, accrued interest on

balances in the Account, and such amounts as may be deposited in, or appropriated to, the Account as provided in this subsection.

(C) Separate from rest of Trust Fund

Funds provided under this subsection to the Account shall be kept separate from all other funds within the Federal Supplementary Medical Insurance Trust Fund, but shall be invested, and such investments redeemed, in the same manner as all other funds and investments within such Trust Fund.

(2) Payments from account

(A) In general

The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make payments for transitional assistance provided under subsections (g) and (j)(2).

(B) Treatment in relation to part B premium

Amounts payable from the Account shall not be taken into account in computing actuarial rates or premium amounts under section 1395r of this title.

(3) Appropriations to cover benefits

There are appropriated to the Account in a fiscal year, out of any moneys in the Treasury not otherwise appropriated, an amount equal to the payments made from the Account in the year.

(4) For administrative expenses

There are authorized to be appropriated to the Secretary such sums as may be necessary to carry out the Secretary’s responsibilities under this section.

(5) Transfer of any remaining balance to Medicare Prescription Drug Account

Any balance remaining in the Account after the Secretary determines that funds in the Account are no longer necessary to carry out the program under this section shall be transferred and deposited into the Medicare Prescription Drug Account under section 1395w-116 of this title.

(6) Construction

Nothing in this section shall be construed as authorizing the Secretary to provide for payment (other than payment of an enrollment fee on behalf of a transitional assistance eligible individual under subsection (g)(1)(A)) to a sponsor for administrative expenses incurred by the sponsor in carrying out this section (including in administering the transitional assistance provisions of subsections (f) and (g)).

(Aug. 14, 1935, ch. 531, title XVIII, §1860D-31, as added Pub. L. 108-173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2131.)

REFERENCES IN TEXT

The Internal Revenue Code of 1986, referred to in subsec. (f)(3)(B)(iii), is classified generally to Title 26, Internal Revenue Code.

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (h)(6)(A), is section 264(c) of Pub. L. 104-191, which is set out as a note under section 1320d-2 of this title.

RULES FOR IMPLEMENTATION

Pub. L. 108-173, title I, §105(c), Dec. 8, 2003, 117 Stat. 2166, provided that: “The following rules shall apply to the medicare prescription drug discount card and transitional assistance program under section 1860D-31 of the Social Security Act [42 U.S.C. 1395w-141], as added by section 101(a):

“(1) In promulgating regulations pursuant to subsection (a)(2)(B) of such section 1860D-31 [42 U.S.C. 1395w-141(a)(2)(B)]—

“(A) section 1871(a)(3) of the Social Security Act (42 U.S.C. 1395hh(a)(3)), as added by section 902(a)(1), shall not apply;

“(B) chapter 35 of title 44, United States Code, shall not apply; and

“(C) sections 553(d) and 801(a)(3)(A) of title 5, United States Code, shall not apply.

“(2) Section 1857(c)(5) of the Social Security Act (42 U.S.C. 1395w-27(c)(5)) shall apply with respect to section 1860D-31 of such Act, as added by section 101(a), in the same manner as it applies to part C of title XVIII of such Act [42 U.S.C. 1395w-21 et seq.].

“(3) The administration of such program shall be made without regard to chapter 35 of title 44, United States Code.

“(4)(A) There shall be no judicial review of a determination not to endorse, or enter into a contract, with a prescription drug card sponsor under section 1860D-31 of the Social Security Act.

“(B) In the case of any order issued to enjoin any provision of section 1860D-31 of the Social Security Act (or of [sic] any provision of this section [amending sections 1395r, 1395t, and 1396r-8 of this title and sections 6103 and 7213 of Title 26, Internal Revenue Code]), such order shall not affect any other provision of such section (or of this section) and all such provisions shall be treated as severable.”

SUBPART 5—DEFINITIONS AND MISCELLANEOUS PROVISIONS

§ 1395w-151. Definitions; treatment of references to provisions in part C**(a) Definitions**

For purposes of this part:

(1) Basic prescription drug coverage

The term “basic prescription drug coverage” is defined in section 1395w-102(a)(3) of this title.

(2) Covered part D drug

The term “covered part D drug” is defined in section 1395w-102(e) of this title.

(3) Creditable prescription drug coverage

The term “creditable prescription drug coverage” has the meaning given such term in section 1395w-113(b)(4) of this title.

(4) Part D eligible individual

The term “part D eligible individual” has the meaning given such term in section 1395w-101(a)(3)(A) of this title.¹

(5) Fallback prescription drug plan

The term “fallback prescription drug plan” has the meaning given such term in section 1395w-111(g)(4) of this title.

(6) Initial coverage limit

The term “initial coverage limit” means such limit as established under section 1395w-102(b)(3) of this title, or, in the case of

coverage that is not standard prescription drug coverage, the comparable limit (if any) established under the coverage.

(7) Insurance risk

The term “insurance risk” means, with respect to a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitution.

(8) MA plan

The term “MA plan” has the meaning given such term in section 1395w-101(a)(3)(B) of this title.¹

(9) MA-PD plan

The term “MA-PD plan” has the meaning given such term in section 1395w-101(a)(3)(C) of this title.¹

(10) Medicare Prescription Drug Account

The term “Medicare Prescription Drug Account” means the Account created under section 1395w-116(a) of this title.

(11) PDP approved bid

The term “PDP approved bid” has the meaning given such term in section 1395w-113(a)(6) of this title.

(12) PDP region

The term “PDP region” means such a region as provided under section 1395w-111(a)(2) of this title.

(13) PDP sponsor

The term “PDP sponsor” means a non-governmental entity that is certified under this part as meeting the requirements and standards of this part for such a sponsor.

(14) Prescription drug plan

The term “prescription drug plan” means prescription drug coverage that is offered—

(A) under a policy, contract, or plan that has been approved under section 1395w-111(e) of this title; and

(B) by a PDP sponsor pursuant to, and in accordance with, a contract between the Secretary and the sponsor under section 1395w-112(b) of this title.

(15) Qualified prescription drug coverage

The term “qualified prescription drug coverage” is defined in section 1395w-102(a)(1) of this title.

(16) Standard prescription drug coverage

The term “standard prescription drug coverage” is defined in section 1395w-102(b) of this title.

(17) State Pharmaceutical Assistance Program

The term “State Pharmaceutical Assistance Program” has the meaning given such term in section 1395w-133(b) of this title.

(18) Subsidy eligible individual

The term “subsidy eligible individual” has the meaning given such term in section 1395w-114(a)(3)(A) of this title.

¹ See References in Text note below.