under this title [see Tables for classification]. The Secretary shall include in the report specific steps that have been taken, and that need to be taken, to ensure a timely start of the program on January 1, 2006. The report shall include recommendations regarding an appropriate transition from the program under section 1860D–31 of the Social Security Act [section 1395w–141 of this title] to prescription drug benefits under subpart 1 of part D of title XVIII of such Act [this subpart].''

STATE PHARMACEUTICAL ASSISTANCE TRANSITION COMMISSION

Pub. L. 108–173, title I, § 106, Dec. 8, 2003, 117 Stat. 2168, provided that:

''(a) ESTABLISHMENT.—

''(1) IN GENERAL.—There is established, as of the first day of the third month beginning after the date of the enactment of this Act [Dec. 8, 2003], a State Pharmaceutical Assistance Transition Commission (in this section referred to as the 'Commission') to develop a proposal for addressing the unique transitional issues facing State pharmaceutical assistance programs, and program participants, due to the implementation of the voluntary prescription drug benefit program under part D of title XVIII of the Social Security Act [this part], as added by section 101.

''(2) DEFINITIONS.—For purposes of this section:

''(A) STATE PHARMACEUTICAL ASSISTANCE PROGRAM DEFINED.—The term 'State pharmaceutical assistance program' means a program (other than the medicaid program) operated by a State (or under contract with a State) that provides as of the date of the enactment of this Act [Dec. 8, 2003] financial assistance to medicare beneficiaries for the purchase of prescription drugs.

''(B) PROGRAM PARTICIPANT.—The term 'program participant' means a low-income medicare beneficiary who is a participant in a State pharmaceutical assistance program.

''(b) COMPOSITION.—The Commission shall include the following:

''(1) A representative of each Governor of each State that the Secretary [of Health and Human Services] identifies as operating on a statewide basis a State pharmaceutical assistance program that provides for eligibility and benefits that are comparable or more generous than the low-income assistance eligibility and benefits offered under section 1860D–14 of the Social Security Act [section 1395w–114 of this title].

''(2) Representatives from other States that the Secretary identifies have in operation other State pharmaceutical assistance programs, as appointed by the Secretary.

''(3) Representatives of organizations that have an inherent interest in program participants or the program itself, as appointed by the Secretary but not to exceed the number of representatives under paragraphs (1) and (2).

''(4) Representatives of Medicare Advantage organizations, pharmaceutical benefit managers, and other private health insurance plans, as appointed by the Secretary.

''(5) The Secretary (or the Secretary's designee) and such other members as the Secretary may specify.

The Secretary shall designate a member to serve as Chair of the Commission and the Commission shall meet at the call of the Chair.

''(c) DEVELOPMENT OF PROPOSAL.—The Commission shall develop the proposal described in subsection (a) in a manner consistent with the following principles:

''(1) Protection of the interests of program participants in a manner that is the least disruptive to such participants and that includes a single point of contact for enrollment and processing of benefits.

''(2) Protection of the financial and flexibility interests of States so that States are not financially worse off as a result of the enactment of this title [see Tables for classification].

''(3) Principles of medicare modernization under this Act [see Tables for classification].

''(d) REPORT.—By not later than January 1, 2005, the Commission shall submit to the President and Congress a report that contains a detailed proposal (including specific legislative or administrative recommendations, if any) and such other recommendations as the Commission deems appropriate.

''(e) SUPPORT.—The Secretary shall provide the Commission with the administrative support services necessary for the Commission to carry out its responsibilities under this section.

''(f) TERMINATION.—The Commission shall terminate 30 days after the date of submission of the report under subsection (d).''

CONFLICT OF INTEREST STUDY

Pub. L. 108–173, title I, § 110, Dec. 8, 2003, 117 Stat. 2174, provided that:

''(a) STUDY.—The Federal Trade Commission shall conduct a study of differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers. Such study shall include the following:

''(1) An assessment of the differences in costs incurred by such enrollees and plans for prescription drugs dispensed by mail-order pharmacies owned by pharmaceutical benefit managers compared to mail-order pharmacies not owned by pharmaceutical benefit managers, and community pharmacies.

''(2) Whether such plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees.

''(b) REPORT.—Not later than 18 months after the date of the enactment of this Act [Dec. 8, 2003], the Commission shall submit to Congress a report on the study conducted under subsection (a). Such report shall include recommendations regarding any need for legislation to ensure the fiscal integrity of the voluntary prescription drug benefit program under part D of title XVIII [this part], as added by section 101, that may be appropriated as the result of such study.

''(c) EXEMPTION FROM PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information under subsection (a).''

§ 1395w–102. Prescription drug benefits

(a) Requirements

(1) In general

For purposes of this part and part C of this subchapter, the term ''qualified prescription drug coverage'' means either of the following:

(A) Standard prescription drug coverage with access to negotiated prices

Standard prescription drug coverage (as defined in subsection (b) of this section) and access to negotiated prices under subsection (d) of this section.

(B) Alternative prescription drug coverage with at least actuarially equivalent benefits and access to negotiated prices

Coverage of covered part D drugs which meets the alternative prescription drug coverage requirements of subsection (c) of this section and access to negotiated prices under subsection (d) of this section, but only if the benefit design of such coverage is approved by the Secretary, as provided under subsection (c) of this section.

(2) Permitting supplemental prescription drug coverage

(A) In general

Subject to subparagraph (B), qualified prescription drug coverage may include supple-

mental prescription drug coverage consisting of either or both of the following:

(i) Certain reductions in cost-sharing

(I) In general

A reduction in the annual deductible, a reduction in the coinsurance percentage, or an increase in the initial coverage limit with respect to covered part D drugs, or any combination thereof, insofar as such a reduction or increase increases the actuarial value of benefits above the actuarial value of basic prescription drug coverage.

(II) Construction

Nothing in this paragraph shall be construed as affecting the application of subsection (c)(3) of this section.

(ii) Optional drugs

Coverage of any product that would be a covered part D drug but for the application of subsection (e)(2)(A) of this section.

(B) Requirement

A PDP sponsor may not offer a prescription drug plan that provides supplemental prescription drug coverage pursuant to subparagraph (A) in an area unless the sponsor also offers a prescription drug plan in the area that only provides basic prescription drug coverage.

(3) Basic prescription drug coverage

For purposes of this part and part C of this subchapter, the term ''basic prescription drug coverage'' means either of the following:

(A) Coverage that meets the requirements of paragraph (1)(A).

(B) Coverage that meets the requirements of paragraph (1)(B) but does not have any supplemental prescription drug coverage described in paragraph (2)(A).

(4) Application of secondary payor provisions

The provisions of section 1395w–22(a)(4) of this title shall apply under this part in the same manner as they apply under part C of this subchapter.

(5) Construction

Nothing in this subsection shall be construed as changing the computation of incurred costs under subsection (b)(4) of this section.

(b) Standard prescription drug coverage

For purposes of this part and part C of this subchapter, the term ''standard prescription drug coverage'' means coverage of covered part D drugs that meets the following requirements:

(1) Deductible

(A) In general

The coverage has an annual deductible—

(i) for 2006, that is equal to $250; or

(ii) for a subsequent year, that is equal to the amount specified under this paragraph for the previous year increased by the percentage specified in paragraph (6) for the year involved.

(B) Rounding

Any amount determined under subparagraph (A)(ii) that is not a multiple of $5 shall be rounded to the nearest multiple of $5.

(2) Benefit structure

(A) 25 percent coinsurance

The coverage has coinsurance (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3)) that is—

(i) equal to 25 percent; or

(ii) actuarially equivalent (using processes and methods established under section 1395w–111(c) of this title) to an average expected payment of 25 percent of such costs.

(B) Use of tiers

Nothing in this part shall be construed as preventing a PDP sponsor or an MA organization from applying tiered copayments under a plan, so long as such tiered copayments are consistent with subparagraph (A)(ii).

(3) Initial coverage limit

(A) In general

Except as provided in paragraph (4), the coverage has an initial coverage limit on the maximum costs that may be recognized for payment purposes (including the annual deductible)—

(i) for 2006, that is equal to $2,250; or

(ii) for a subsequent year, that is equal to the amount specified in this paragraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

(B) Rounding

Any amount determined under subparagraph (A)(ii) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(4) Protection against high out-of-pocket expenditures

(A) In general

(i) In general

The coverage provides benefits, after the part D eligible individual has incurred costs (as described in subparagraph (C)) for covered part D drugs in a year equal to the annual out-of-pocket threshold specified in subparagraph (B), with cost-sharing that is equal to the greater of—

(I) a copayment of $2 for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1396r–8(k)(7)(A)(i) of this title) and $5 for any other drug; or

(II) coinsurance that is equal to 5 percent.

(ii) Adjustment of amount

For a year after 2006, the dollar amounts specified in clause (i)(I) shall be equal to the dollar amounts specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved. Any amount established under this clause that is not a multiple of a 5 cents

shall be rounded to the nearest multiple of 5 cents.

(B) Annual out-of-pocket threshold

(i) In general

For purposes of this part, the ''annual out-of-pocket threshold'' specified in this subparagraph—

(I) for 2006, is equal to $3,600; or

(II) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

(ii) Rounding

Any amount determined under clause (i)(II) that is not a multiple of $50 shall be rounded to the nearest multiple of $50.

(C) Application

In applying subparagraph (A)—

(i) incurred costs shall only include costs incurred with respect to covered part D drugs for the annual deductible described in paragraph (1), for cost-sharing described in paragraph (2), and for amounts for which benefits are not provided because of the application of the initial coverage limit described in paragraph (3), but does not include any costs incurred for covered part D drugs which are not included (or treated as being included) in the plan's formulary; and

(ii) such costs shall be treated as incurred only if they are paid by the part D eligible individual (or by another person, such as a family member, on behalf of the individual), under section 1395w–114 of this title, or under a State Pharmaceutical Assistance Program and the part D eligible individual (or other person) is not reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement (other than under such section or such a Program) for such costs.

(D) Information regarding third-party reimbursement

(i) Procedures for exchanging information

In order to accurately apply the requirements of subparagraph (C)(ii), the Secretary is authorized to establish procedures, in coordination with the Secretary of the Treasury and the Secretary of Labor—

(I) for determining whether costs for part D eligible individuals are being reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement; and

(II) for alerting the PDP sponsors and MA organizations that offer the prescription drug plans and MA–PD plans in which such individuals are enrolled about such reimbursement arrangements.

(ii) Authority to request information from enrollees

A PDP sponsor or an MA organization may periodically ask part D eligible individuals enrolled in a prescription drug plan or an MA–PD plan offered by the sponsor or organization whether such individuals have or expect to receive such third-party reimbursement. A material misrepresentation of the information described in the preceding sentence by an individual (as defined in standards set by the Secretary and determined through a process established by the Secretary) shall constitute grounds for termination of enrollment in any plan under section 1395w–21(g)(3)(B) of this title (and as applied under this part under section 1395w–101(b)(1)(B)(v) of this title) for a period specified by the Secretary.

(5) Construction

Nothing in this part shall be construed as preventing a PDP sponsor or an MA organization offering an MA–PD plan from reducing to zero the cost-sharing otherwise applicable to preferred or generic drugs.

(6) Annual percentage increase

The annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered part D drugs in the United States for part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify.

(c) Alternative prescription drug coverage requirements

A prescription drug plan or an MA–PD plan may provide a different prescription drug benefit design from standard prescription drug coverage so long as the Secretary determines (consistent with section 1395w–111(c) of this title) that the following requirements are met and the plan applies for, and receives, the approval of the Secretary for such benefit design:

(1) Assuring at least actuarially equivalent coverage

(A) Assuring equivalent value of total coverage

The actuarial value of the total coverage is at least equal to the actuarial value of standard prescription drug coverage.

(B) Assuring equivalent unsubsidized value of coverage

The unsubsidized value of the coverage is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under section 1395w–115 of this title with respect to such coverage.

(C) Assuring standard payment for costs at initial coverage limit

The coverage is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under subsection (b)(3)

of this section for the year, of an amount equal to at least the product of—

(i) the amount by which the initial coverage limit described in subsection (b)(3) of this section for the year exceeds the deductible described in subsection (b)(1) of this section for the year; and

(ii) 100 percent minus the coinsurance percentage specified in subsection (b)(2)(A)(i) of this section.

(2) Maximum required deductible

The deductible under the coverage shall not exceed the deductible amount specified under subsection (b)(1) of this section for the year.

(3) Same protection against high out-of-pocket expenditures

The coverage provides the coverage required under subsection (b)(4) of this section.

(d) Access to negotiated prices

(1) Access

(A) In general

Under qualified prescription drug coverage offered by a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan, the sponsor or organization shall provide enrollees with access to negotiated prices used for payment for covered part D drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of a deductible or other cost-sharing or an initial coverage limit (described in subsection (b)(3) of this section).

(B) Negotiated prices

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

(C) Medicaid-related provisions

The prices negotiated by a prescription drug plan, by an MA–PD plan with respect to covered part D drugs, or by a qualified retiree prescription drug plan (as defined in section 1395w–132(a)(2) of this title) with respect to such drugs on behalf of part D eligible individuals, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1395r–8(c)(1)(C) of this title.

(2) Disclosure

A PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan shall disclose to the Secretary (in a manner specified by the Secretary) the aggregate negotiated price concessions described in paragraph (1)(B) made available to the sponsor or organization by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers. The provisions of section 1396r–8(b)(3)(D) of this title apply to information disclosed to the Secretary under this paragraph.

(3) Audits

To protect against fraud and abuse and to ensure proper disclosures and accounting under this part and in accordance with section 1395w–27(d)(2)(B) of this title (as applied under section 1395w–112(b)(3)(C) of this title), the Secretary may conduct periodic audits, directly or through contracts, of the financial statements and records of PDP sponsors with respect to prescription drug plans and MA organizations with respect to MA–PD plans.

(e) Covered part D drug defined

(1) In general

Except as provided in this subsection, for purposes of this part, the term ''covered part D drug'' means—

(A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1396r–8(k)(2) of this title; or

(B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary),

and such term includes a vaccine licensed under section 262 of this title (and, for vaccines administered on or after January 1, 2008, its administration) and any use of a covered part D drug for a medically accepted indication (as defined in paragraph (4)).

(2) Exclusions

(A) In general

Such term does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1396r–8(d)(2) of this title, other than subparagraph (E) of such section (relating to smoking cessation agents), other than subparagraph (I) of such section (relating to barbiturates) if the barbiturate is used in the treatment of epilepsy, cancer, or a chronic mental health disorder, and other than subparagraph (J) of such section (relating to benzodiazepines), or under section 1396r–8(d)(3) of this title, as such sections were in effect on December 8, 2003. Such term also does not include a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration.

(B) Medicare covered drugs

A drug prescribed for a part D eligible individual that would otherwise be a covered part D drug under this part shall not be so considered if payment for such drug as so prescribed and dispensed or administered with respect to that individual is available (or would be available but for the application of a deductible) under part A or B of this subchapter for that individual.

(3) Application of general exclusion provisions

A prescription drug plan or an MA–PD plan may exclude from qualified prescription drug coverage any covered part D drug—

(A) for which payment would not be made if section 1395y(a) of this title applied to this part; or

(B) which is not prescribed in accordance with the plan or this part.

Such exclusions are determinations subject to reconsideration and appeal pursuant to subsections (g) and (h), respectively, of section 1395w–104 of this title.

(4) Medically accepted indication defined

(A) In general

For purposes of paragraph (1), the term ''medically accepted indication'' has the meaning given that term—

(i) in the case of a covered part D drug used in an anticancer chemotherapeutic regimen, in section 1395x(t)(2)(B) of this title, except that in applying such section—

(I) ''prescription drug plan or MA–PD plan'' shall be substituted for ''carrier'' each place it appears; and

(II) subject to subparagraph (B), the compendia described in section 1396r–8(g)(1)(B)(i)(III) of this title shall be included in the list of compendia described in clause (ii)(I) section 1395x(t)(2)(B) of this title; and

(ii) in the case of any other covered part D drug, in section 1396r–8(k)(6) of this title.

(B) Conflict of interest

On and after January 1, 2010, subparagraph (A)(i)(II) shall not apply unless the compendia described in section 1396r–8(g)(1)(B)(i)(III) of this title meets[1] the requirement in the third sentence of section 1395x(t)(2)(B) of this title.

(C) Update

For purposes of applying subparagraph (A)(ii), the Secretary shall revise the list of compendia described in section 1396r–8(g)(1)(B)(i) of this title as is appropriate for identifying medically accepted indications for drugs. Any such revision shall be done in a manner consistent with the process for revising compendia under section 1395x(t)(2)(B) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D–2, as added Pub. L. 108–173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2075; amended Pub. L. 109–91, title I, §103(a), Oct. 20, 2005, 119 Stat. 2092; Pub. L. 109–432, div. B, title II, §202(b), Dec. 20, 2006, 120 Stat. 2986; Pub. L. 110–275, title I, §§175(a), 182(a)(1), July 15, 2008, 122 Stat. 2581, 2583.)

REFERENCES IN TEXT

Part C of this subchapter, referred to in subsecs. (a)(1), (3), (4) and (b), is classified to section 1395w–21 et seq. of this title.

Parts A and B of this subchapter, referred to in subsec. (e)(2)(B), are classified to sections 1395c et seq. and 1395j et seq., respectively, of this title.

[1] So in original. Probably should be ''meet''.

AMENDMENTS

2008—Subsec. (e)(1). Pub. L. 110–275, §182(a)(1)(A), substituted ''(as defined in paragraph (4))'' for ''(as defined in section 1396r–8(k)(6) of this title)'' in concluding provisions.

Subsec. (e)(2)(A). Pub. L. 110–275, §175(a), inserted ''other than subparagraph (I) of such section (relating to barbiturates) if the barbiturate is used in the treatment of epilepsy, cancer, or a chronic mental health disorder, and other than subparagraph (J) of such section (relating to benzodiazepines),'' after ''agents),''.

Subsec. (e)(4). Pub. L. 110–275, §182(a)(1)(B), which directed amendment of subsec. (e)(1) in the matter following subpar. (B) by adding par. (4) at the end, was executed by adding par. (4) at end of subsec. (e), to reflect the probable intent of Congress.

2006—Subsec. (e)(1). Pub. L. 109–432 inserted ''(and, for vaccines administered on or after January 1, 2008, its administration)'' after ''section 262 of this title'' in concluding provisions.

2005—Subsec. (e)(2)(A). Pub. L. 109–91, §103(a)(2), inserted at end ''Such term also does not include a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration.''

Pub. L. 109–91, §103(a)(1), inserted before period at end '', as such sections were in effect on December 8, 2003''.

EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110–275, title I, §175(b), July 15, 2008, 122 Stat. 2581, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to prescriptions dispensed on or after January 1, 2013.''

Pub. L. 110–275, title I, §182(a)(2), July 15, 2008, 122 Stat. 2583, provided that: ''The amendments made by this subsection [amending this section] shall apply to plan years beginning on or after January 1, 2009.''

EFFECTIVE DATE OF 2005 AMENDMENT

Pub. L. 109–91, title I, §103(c), Oct. 20, 2005, 119 Stat. 2092, provided that: ''The amendment made by subsection (a)(1) [amending this section] shall take effect as if included in the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) and the amendment made by subsection (a)(2) [amending this section] shall apply to coverage for drugs dispensed on or after January 1, 2007.''

CONSTRUCTION

Pub. L. 109–91, title I, §103(b), Oct. 20, 2005, 119 Stat. 2092, provided that: ''Nothing in this section [amending this section and enacting provisions set out as a note under this section] shall be construed as preventing a prescription drug plan or an MA–PD plan from providing coverage of drugs for the treatment of sexual or erectile dysfunction as supplemental prescription drug coverage under section 1860D–2(a)(2)(A)(ii) of the Social Security Act (42 U.S.C. 1395w–102(a)(2)(A)(ii)).''

PAYMENT FOR ADMINISTRATION OF PART D VACCINES IN 2007

Pub. L. 109–432, div. B, title II, §202(a), Dec. 20, 2006, 120 Stat. 2986, provided that: ''Notwithstanding any other provision of law, in the case of a vaccine that is a covered part D drug under section 1860D–2(e) of the Social Security Act (42 U.S.C. 1395w–102(e)) and that is administered during 2007, the administration of such vaccine shall be paid under part B of title XVIII of such Act [part B of this subchapter] as if it were the administration of a vaccine described in section 1861(s)(10)(B) of such Act (42 U.S.C. 1395w(s)(10)(B) [probably should be 1395x(s)(10)(B)]).''

§ 1395w–103. Access to a choice of qualified prescription drug coverage

(a) Assuring access to a choice of coverage

(1) Choice of at least two plans in each area

The Secretary shall ensure that each part D eligible individual has available, consistent with paragraph (2), a choice of enrollment in at least 2 qualifying plans (as defined in paragraph (3)) in the area in which the individual resides, at least one of which is a prescription drug plan. In any such case in which such plans are not available, the part D eligible individual shall be given the opportunity to enroll in a fallback prescription drug plan.

(2) Requirement for different plan sponsors

The requirement in paragraph (1) is not satisfied with respect to an area if only one entity offers all the qualifying plans in the area.

(3) Qualifying plan defined

For purposes of this section, the term ''qualifying plan'' means—

(A) a prescription drug plan; or

(B) an MA–PD plan described in section 1395w–21(a)(2)(A)(i) of this title that provides—

(i) basic prescription drug coverage; or

(ii) qualified prescription drug coverage that provides supplemental prescription drug coverage so long as there is no MA monthly supplemental beneficiary premium applied under the plan, due to the application of a credit against such premium of a rebate under section 1395w–24(b)(1)(C) of this title.

(b) Flexibility in risk assumed and application of fallback plan

In order to ensure access pursuant to subsection (a) of this section in an area—

(1) the Secretary may approve limited risk plans under section 1395w–111(f) of this title for the area; and

(2) only if such access is still not provided in the area after applying paragraph (1), the Secretary shall provide for the offering of a fallback prescription drug plan for that area under section 1395w–111(g) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D–3, as added Pub. L. 108–173, title I, § 101(a)(2), Dec. 8, 2003, 117 Stat. 2081.)

§ 1395w–104. Beneficiary protections for qualified prescription drug coverage

(a) Dissemination of information

(1) General information

(A) Application of MA information

A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part at the time of enrollment and at least annually thereafter, the information described in section 1395w–22(c)(1) of this title relating to such plan, insofar as the Secretary determines appropriate with respect to benefits provided under this part, and including the information described in subparagraph (B).

(B) Drug specific information

The information described in this subparagraph is information concerning the following:

(i) Access to specific covered part D drugs, including access through pharmacy networks.

(ii) How any formulary (including any tiered formulary structure) used by the sponsor functions, including a description of how a part D eligible individual may obtain information on the formulary consistent with paragraph (3).

(iii) Beneficiary cost-sharing requirements and how a part D eligible individual may obtain information on such requirements, including tiered or other copayment level applicable to each drug (or class of drugs), consistent with paragraph (3).

(iv) The medication therapy management program required under subsection (c) of this section.

(2) Disclosure upon request of general coverage, utilization, and grievance information

Upon request of a part D eligible individual who is eligible to enroll in a prescription drug plan, the PDP sponsor offering such plan shall provide information similar (as determined by the Secretary) to the information described in subparagraphs (A), (B), and (C) of section 1395w–22(c)(2) of this title to such individual.

(3) Provision of specific information

(A) Response to beneficiary questions

Each PDP sponsor offering a prescription drug plan shall have a mechanism for providing specific information on a timely basis to enrollees upon request. Such mechanism shall include access to information through the use of a toll-free telephone number and, upon request, the provision of such information in writing.

(B) Availability of information on changes in formulary through the Internet

A PDP sponsor offering a prescription drug plan shall make available on a timely basis through an Internet website information on specific changes in the formulary under the plan (including changes to tiered or preferred status of covered part D drugs).

(4) Claims information

A PDP sponsor offering a prescription drug plan must furnish to each enrollee in a form easily understandable to such enrollees—

(A) an explanation of benefits (in accordance with section 1395b–7(a) of this title or in a comparable manner); and

(B) when prescription drug benefits are provided under this part, a notice of the benefits in relation to—

(i) the initial coverage limit for the current year; and

(ii) the annual out-of-pocket threshold for the current year.

Notices under subparagraph (B) need not be provided more often than as specified by the