viduals, see section 231(d) of Pub. L. 108–173, set out as a note under section 1395w–21 of this title.

§ 1395w–29. Repealed. Pub. L. 111–152, title I, § 1102(f), Mar. 30, 2010, 124 Stat. 1046

Section, act Aug. 14, 1935, ch. 531, title XVIII, § 1860C–1, as added Pub. L. 108–173, title II, § 241(a), Dec. 8, 2003, 117 Stat. 2214; amended Pub. L. 111–148, title III, § 3201(a)(2)(D), Mar. 23, 2010, 124 Stat. 444; Pub. L. 111–152, title I, § 1102(a), Mar. 30, 2010, 124 Stat. 1040, related to comparative cost adjustment program.

PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

Editorial Notes

PRIOR PROVISIONS

A prior part D of this subchapter, consisting of section 1395x et seq., was redesignated part E of this subchapter.

SUBPART 1—PART D ELIGIBLE INDIVIDUALS AND PRESCRIPTION DRUG BENEFITS

§ 1395w–101. Eligibility, enrollment, and information

(a) Provision of qualified prescription drug coverage through enrollment in plans

(1) In general

Subject to the succeeding provisions of this part, each part D eligible individual (as defined in paragraph (3)(A)) is entitled to obtain qualified prescription drug coverage (described in section 1395w–102(a) of this title) as follows:

(A) Fee-for-service enrollees may receive coverage through a prescription drug plan

A part D eligible individual who is not enrolled in an MA plan may obtain qualified prescription drug coverage through enrollment in a prescription drug plan (as defined in section 1395w–151(a)(14) of this title).

(B) Medicare Advantage enrollees

(i) Enrollees in a plan providing qualified prescription drug coverage receive coverage through the plan

A part D eligible individual who is enrolled in an MA–PD plan obtains such coverage through such plan.

(ii) Limitation on enrollment of MA plan enrollees in prescription drug plans

Except as provided in clauses (iii) and (iv), a part D eligible individual who is enrolled in an MA plan may not enroll in a prescription drug plan under this part.

(iii) Private fee-for-service enrollees in MA plans not providing qualified prescription drug coverage permitted to enroll in a prescription drug plan

A part D eligible individual who is enrolled in an MA private fee-for-service plan (as defined in section 1395w–28(b)(2) of this title) that does not provide qualified prescription drug coverage may obtain qualified prescription drug coverage through enrollment in a prescription drug plan.

(iv) Enrollees in MSA plans permitted to enroll in a prescription drug plan

A part D eligible individual who is enrolled in an MSA plan (as defined in section 1395w–28(b)(3) of this title) may obtain qualified prescription drug coverage through enrollment in a prescription drug plan.

(2) Coverage first effective January 1, 2006

Coverage under prescription drug plans and MA–PD plans shall first be effective on January 1, 2006.

(3) Definitions

For purposes of this part:

(A) Part D eligible individual

The term ''part D eligible individual'' means an individual who is entitled to benefits under part A or enrolled under part B (but not including an individual enrolled solely for coverage of immunosuppressive drugs under section 1395*o*(b) of this title).

(B) MA plan

The term ''MA plan'' has the meaning given such term in section 1395w–28(b)(1) of this title.

(C) MA–PD plan

The term ''MA–PD plan'' means an MA plan that provides qualified prescription drug coverage.

(b) Enrollment process for prescription drug plans

(1) Establishment of process

(A) In general

The Secretary shall establish a process for the enrollment, disenrollment, termination, and change of enrollment of part D eligible individuals in prescription drug plans consistent with this subsection.

(B) Application of MA rules

In establishing such process, the Secretary shall use rules similar to (and coordinated with) the rules for enrollment, disenrollment, termination, and change of enrollment with an MA–PD plan under the following provisions of section 1395w–21 of this title:

(i) Residence requirements

Section 1395w–21(b)(1)(A) of this title, relating to residence requirements.

(ii) Exercise of choice

Section 1395w–21(c) of this title (other than paragraph (3)(A) and paragraph (4) of such section), relating to exercise of choice.

(iii) Coverage election periods

Subject to paragraphs (2) and (3) of this subsection, section 1395w–21(e) of this title (other than subparagraphs (B), (C), (E), and (F) of paragraph (2) and the second sentence of paragraph (4) of such section), relating to coverage election periods, including initial periods, annual coordinated election periods, special election periods, and election periods for exceptional circumstances.

(iv) Coverage periods

Section 1395w–21(f) of this title, relating to effectiveness of elections and changes of elections.

(v) Guaranteed issue and renewal

Section 1395w–21(g) of this title (other than paragraph (2) of such section and clause (i) and the second sentence of clause (ii) of paragraph (3)(C) of such section), relating to guaranteed issue and renewal.

(vi) Marketing material and application forms

Section 1395w–21(h) of this title, relating to approval of marketing material and application forms.

In applying clauses (ii), (iv), and (v) of this subparagraph, any reference to section 1395w–21(e) of this title shall be treated as a reference to such section as applied pursuant to clause (iii) of this subparagraph.

(C) Special rule

The process established under subparagraph (A) shall include, except as provided in subparagraph (D), in the case of a part D eligible individual who is a full-benefit dual eligible individual (as defined in section 1396u–5(c)(6) of this title) who has failed to enroll in a prescription drug plan or an MA–PD plan, for the enrollment in a prescription drug plan that has a monthly beneficiary premium that does not exceed the premium assistance available under section 1395w–114(a)(1)(A) of this title).[1] If there is more than one such plan available, the Secretary shall enroll such an individual on a random basis among all such plans in the PDP region. Nothing in the previous sentence shall prevent such an individual from declining or changing such enrollment.

(D) Special rule for plans that waive de minimis premiums

The process established under subparagraph (A) may include, in the case of a part D eligible individual who is a subsidy eligible individual (as defined in section 1395w–114(a)(3) of this title) who has failed to enroll in a prescription drug plan or an MA–PD plan, for the enrollment in a prescription drug plan or MA–PD plan that has waived the monthly beneficiary premium for such subsidy eligible individual under section 1395w–114(a)(5) of this title. If there is more than one such plan available, the Secretary shall enroll such an individual under the preceding sentence on a random basis among all such plans in the PDP region. Nothing in the previous sentence shall prevent such an individual from declining or changing such enrollment.

(2) Initial enrollment period

(A) Program initiation

In the case of an individual who is a part D eligible individual as of November 15, 2005, there shall be an initial enrollment period that shall be the same as the annual, coordinated open election period described in section 1395w–21(e)(3)(B)(iii) of this title, as applied under paragraph (1)(B)(iii).

(B) Continuing periods

In the case of an individual who becomes a part D eligible individual after November 15, 2005, there shall be an initial enrollment period which is the period under section 1395w–21(e)(1) of this title, as applied under paragraph (1)(B)(iii) of this section,[2] as if ''entitled to benefits under part A or enrolled under part B'' were substituted for ''entitled to benefits under part A and enrolled under part B'', but in no case shall such period end before the period described in subparagraph (A).

(3) Additional special enrollment periods

The Secretary shall establish special enrollment periods, including the following:

(A) Involuntary loss of creditable prescription drug coverage

(i) In general

In the case of a part D eligible individual who involuntarily loses creditable prescription drug coverage (as defined in section 1395w–113(b)(4) of this title).

(ii) Notice

In establishing special enrollment periods under clause (i), the Secretary shall take into account when the part D eligible individuals are provided notice of the loss of creditable prescription drug coverage.

(iii) Failure to pay premium

For purposes of clause (i), a loss of coverage shall be treated as voluntary if the coverage is terminated because of failure to pay a required beneficiary premium.

(iv) Reduction in coverage

For purposes of clause (i), a reduction in coverage so that the coverage no longer meets the requirements under section 1395w–113(b)(5) of this title (relating to actuarial equivalence) shall be treated as an involuntary loss of coverage.

(B) Errors in enrollment

In the case described in section 1395p(h) of this title (relating to errors in enrollment), in the same manner as such section applies to part B.

(C) Exceptional circumstances

In the case of part D eligible individuals who meet such exceptional conditions (in addition to those conditions applied under paragraph (1)(B)(iii)) as the Secretary may provide.

(D) Medicaid coverage

In the case of an individual (as determined by the Secretary, subject to such limits as the Secretary may establish for individuals identified pursuant to section 1395w–104(c)(5) of this title) who is a full-benefit dual eligible individual (as defined in section 1396u–5(c)(6) of this title).

(E) Discontinuance of MA–PD election during first year of eligibility

In the case of a part D eligible individual who discontinues enrollment in an MA–PD

[1] So in original. The closing parenthesis probably should not appear.

[2] So in original. Probably should be ''of this subsection,''.

plan under the second sentence of section 1395w–21(e)(4) of this title at the time of the election of coverage under such sentence under the original medicare fee-for-service program.

(4) Information to facilitate enrollment

(A) In general

Notwithstanding any other provision of law but subject to subparagraph (B), the Secretary may provide to each PDP sponsor and MA organization such identifying information about part D eligible individuals as the Secretary determines to be necessary to facilitate efficient marketing of prescription drug plans and MA–PD plans to such individuals and enrollment of such individuals in such plans.

(B) Limitation

(i) Provision of information

The Secretary may provide the information under subparagraph (A) only to the extent necessary to carry out such subparagraph.

(ii) Use of information

Such information provided by the Secretary to a PDP sponsor or an MA organization may be used by such sponsor or organization only to facilitate marketing of, and enrollment of part D eligible individuals in, prescription drug plans and MA–PD plans.

(5) Reference to enrollment procedures for MA–PD plans

For rules applicable to enrollment, disenrollment, termination, and change of enrollment of part D eligible individuals in MA–PD plans, see section 1395w–21 of this title.

(6) Reference to penalties for late enrollment

Section 1395w–113(b) of this title imposes a late enrollment penalty for part D eligible individuals who—

(A) enroll in a prescription drug plan or an MA–PD plan after the initial enrollment period described in paragraph (2); and

(B) fail to maintain continuous creditable prescription drug coverage during the period of non-enrollment.

(c) Providing information to beneficiaries

(1) Activities

The Secretary shall conduct activities that are designed to broadly disseminate information to part D eligible individuals (and prospective part D eligible individuals) regarding the coverage provided under this part. Such activities shall ensure that such information is first made available at least 30 days prior to the initial enrollment period described in subsection (b)(2)(A).

(2) Requirements

The activities described in paragraph (1) shall—

(A) be similar to the activities performed by the Secretary under section 1395w–21(d) of this title, including dissemination (including through the toll-free telephone number 1–800–MEDICARE) of comparative information for prescription drug plans and MA–PD plans; and

(B) be coordinated with the activities performed by the Secretary under such section and under section 1395b–2 of this title.

(3) Comparative information

(A) In general

Subject to subparagraph (B), the comparative information referred to in paragraph (2)(A) shall include a comparison of the following with respect to qualified prescription drug coverage:

(i) Benefits

The benefits provided under the plan.

(ii) Monthly beneficiary premium

The monthly beneficiary premium under the plan.

(iii) Quality and performance

The quality and performance under the plan.

(iv) Beneficiary cost-sharing

The cost-sharing required of part D eligible individuals under the plan.

(v) Consumer satisfaction surveys

The results of consumer satisfaction surveys regarding the plan conducted pursuant to section 1395w–104(d) of this title.

(B) Exception for unavailability of information

The Secretary is not required to provide comparative information under clauses (iii) and (v) of subparagraph (A) with respect to a plan—

(i) for the first plan year in which it is offered; and

(ii) for the next plan year if it is impracticable or the information is otherwise unavailable.

(4) Information on late enrollment penalty

The information disseminated under paragraph (1) shall include information concerning the methodology for determining the late enrollment penalty under section 1395w–113(b) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D–1, as added Pub. L. 108–173, title I, § 101(a)(2), Dec. 8, 2003, 117 Stat. 2071; amended Pub. L. 109–432, div. B, title II, § 206(b), Dec. 20, 2006, 120 Stat. 2990; Pub. L. 111–148, title III, § 3303(b), Mar. 23, 2010, 124 Stat. 469; Pub. L. 114–10, title II, § 209(b)(2)(B)(ii), Apr. 16, 2015, 129 Stat. 149; Pub. L. 114–198, title VII, § 704(a)(3), July 22, 2016, 130 Stat. 748; Pub. L. 116–260, div. CC, title IV, § 402(g), Dec. 27, 2020, 134 Stat. 3002.)

Editorial Notes

AMENDMENTS

2020—Subsec. (a)(3)(A). Pub. L. 116–260 inserted ''(but not including an individual enrolled solely for coverage of immunosuppressive drugs under section 1395*o*(b) of this title)'' before period at end.

2016—Subsec. (b)(3)(D). Pub. L. 114–198 inserted '', subject to such limits as the Secretary may estab-

lish for individuals identified pursuant to section 1395w–104(c)(5) of this title'' after ''the Secretary''.

2015—Subsec. (b)(1)(B)(ii). Pub. L. 114–10, § 209(b)(2)(B)(ii)(I), inserted ''and paragraph (4)'' after ''paragraph (3)(A)''.

Subsec. (b)(1)(B)(iii). Pub. L. 114–10, § 209(b)(2)(B)(ii)(II), substituted ''(E), and (F)'' for ''and (E)''.

2010—Subsec. (b)(1)(C). Pub. L. 111–148, § 3303(b)(1), inserted ''except as provided in subparagraph (D),'' after ''shall include,''.

Subsec. (b)(1)(D). Pub. L. 111–148, § 3303(b)(2), added subpar. (D).

2006—Subsec. (b)(1)(B)(iii). Pub. L. 109–432 substituted ''subparagraphs (B), (C), and (E)'' for ''subparagraphs (B) and (C)''.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2016 AMENDMENT

Pub. L. 114–198, title VII, § 704(g)(1), July 22, 2016, 130 Stat. 751, provided that: ''The amendments made by this section [amending this section and sections 1395w–104, 1395w–152, 1395ddd, and 1395iii of this title] shall apply to prescription drug plans (and MA–PD plans) for plan years beginning on or after January 1, 2019.''

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, § 3303(c), Mar. 23, 2010, 124 Stat. 469, provided that: ''The amendments made by this subsection [probably should be ''this section'', amending this section and section 1395w–114 of this title] shall apply to premiums for months, and enrollments for plan years, beginning on or after January 1, 2011.''

REGULATIONS

Pub. L. 114–198, title VII, § 704(g)(2), (3), July 22, 2016, 130 Stat. 751, 752, provided that:

''(2) STAKEHOLDER MEETINGS PRIOR TO EFFECTIVE DATE.—

''(A) IN GENERAL.—Not later than January 1, 2017, the Secretary of Health and Human Services shall convene stakeholders, including individuals entitled to benefits under part A of title XVIII of the Social Security Act [42 U.S.C. 1395c et seq.] or enrolled under part B of such title [42 U.S.C. 1395j et seq.], advocacy groups representing such individuals, physicians, pharmacists, and other clinicians, retail pharmacies, plan sponsors, entities delegated by plan sponsors, and biopharmaceutical manufacturers for input regarding the topics described in subparagraph (B). The input described in the preceding sentence shall be provided to the Secretary in sufficient time in order for the Secretary to take such input into account in promulgating the regulations pursuant to paragraph (3).

''(B) TOPICS DESCRIBED.—The topics described in this subparagraph are the topics of—

''(i) the anticipated impact of drug management programs for at-risk beneficiaries under paragraph (5) of section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) on cost-sharing and ensuring accessibility to prescription drugs for enrollees in prescription drug plans of PDP sponsors, and enrollees in MA–PD plans, who are at-risk beneficiaries for prescription drug abuse (as defined in subparagraph (C) of such paragraph);

''(ii) the use of an expedited appeals process under which such an enrollee may appeal an identification of such enrollee as an at-risk beneficiary for prescription drug abuse under such paragraph (similar to the processes established under the Medicare Advantage program under part C of title XVIII of the Social Security Act [42 U.S.C. 1395w–21 et seq.] that allow an automatic escalation to external review of claims submitted under such part);

''(iii) the types of enrollees that should be treated as exempted individuals, as described in subparagraph (C)(ii) of such paragraph;

''(iv) the manner in which terms and definitions in such paragraph should be applied, such as the use of clinical appropriateness in determining whether an enrollee is an at-risk beneficiary for prescription drug abuse as defined in subparagraph (C) of such paragraph;

''(v) the information to be included in the notices described in subparagraph (B) of such paragraph and the standardization of such notices;

''(vi) with respect to a PDP sponsor (or Medicare Advantage organization) that establishes a drug management program for at-risk beneficiaries under such paragraph, the responsibilities of such PDP sponsor (or organization) with respect to the implementation of such program;

''(vii) notices for plan enrollees at the point of sale that would explain why an at-risk beneficiary has been prohibited from receiving a prescription at a location outside of the designated pharmacy;

''(viii) evidence-based prescribing guidelines for opiates; and

''(ix) the sharing of claims data under parts A and B of title XVIII of the Social Security Act [42 U.S.C. 1395c et seq., 1395j et seq.] with PDP sponsors.

''(3) RULEMAKING.—Not later than one year after the date of the enactment of this Act [July 22, 2016], the Secretary of Health and Human Services shall, taking into account the input gathered pursuant to paragraph (2)(A) and after providing notice and an opportunity to comment, promulgate regulations to carry out the provisions of, and amendments made by[,] this section [amending this section and sections 1395w–104, 1395w–152, 1395ddd, and 1395iii of this title and enacting provisions set out as a note above].''

OFFICE OF THE INSPECTOR GENERAL STUDIES AND REPORTS

Pub. L. 111–148, title III, § 3313, Mar. 23, 2010, 124 Stat. 477, provided that:

''(a) STUDY AND ANNUAL REPORT ON PART D FORMULARIES' INCLUSION OF DRUGS COMMONLY USED BY DUAL ELIGIBLES.—

''(1) STUDY.—The Inspector General of the Department of Health and Human Services shall conduct a study of the extent to which formularies used by prescription drug plans and MA–PD plans under part D [42 U.S.C. 1395w–101 et seq.] include drugs commonly used by full-benefit dual eligible individuals (as defined in section 1935(c)(6) of the Social Security Act (42 U.S.C. 1396u–5(c)(6))).

''(2) ANNUAL REPORTS.—Not later than July 1 of each year (beginning with 2011), the Inspector General shall submit to Congress a report on the study conducted under paragraph (1), together with such recommendations as the Inspector General determines appropriate.

''(b) STUDY AND REPORT ON PRESCRIPTION DRUG PRICES UNDER MEDICARE PART D AND MEDICAID.—

''(1) STUDY.—

''(A) IN GENERAL.—The Inspector General of the Department of Health and Human Services shall conduct a study on prices for covered part D drugs under the Medicare prescription drug program under part D of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq.] and for covered outpatient drugs under title XIX [42 U.S.C. 1396 et seq.]. Such study shall include the following:

''(i) A comparison, with respect to the 200 most frequently dispensed covered part D drugs under such program and covered outpatient drugs under such title (as determined by the Inspector General based on volume and expenditures), of—

''(I) the prices paid for covered part D drugs by PDP sponsors of prescription drug plans and Medicare Advantage organizations offering MA–PD plans; and

''(II) the prices paid for covered outpatient drugs by a State plan under title XIX.

''(ii) An assessment of—

''(I) the financial impact of any discrepancies in such prices on the Federal Government; and

''(II) the financial impact of any such discrepancies on enrollees under part D or individuals eligible for medical assistance under a State plan under title XIX.

''(B) PRICE.—For purposes of subparagraph (A), the price of a covered part D drug or a covered outpatient drug shall include any rebate or discount under such program or such title, respectively, including any negotiated price concession described in section 1860D–2(d)(1)(B) of the Social Security Act (42 U.S.C. 1395w–102(d)(1)(B)) or rebate under an agreement under section 1927 of the Social Security Act (42 U.S.C. 1396r–8).

''(C) AUTHORITY TO COLLECT ANY NECESSARY INFORMATION.—Notwithstanding any other provision of law, the Inspector General of the Department of Health and Human Services shall be able to collect any information related to the prices of covered part D drugs under such program and covered outpatient drugs under such title XIX necessary to carry out the comparison under subparagraph (A).

''(2) REPORT.—

''(A) IN GENERAL.—Not later than October 1, 2011, subject to subparagraph (B), the Inspector General shall submit to Congress a report containing the results of the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Inspector General determines appropriate.

''(B) LIMITATION ON INFORMATION CONTAINED IN REPORT.—The report submitted under subparagraph (A) shall not include any information that the Inspector General determines is proprietary or is likely to negatively impact the ability of a PDP sponsor or a State plan under title XIX [42 U.S.C. 1396 et seq.] to negotiate prices for covered part D drugs or covered outpatient drugs, respectively.

''(3) DEFINITIONS.—In this section:

''(A) COVERED PART D DRUG.—The term 'covered part D drug' has the meaning given such term in section 1860D–2(e) of the Social Security Act (42 U.S.C. 1395w–102(e)).

''(B) COVERED OUTPATIENT DRUG.—The term 'covered outpatient drug' has the meaning given such term in section 1927(k) of such Act (42 U.S.C. 1396r[–8](k)).

''(C) MA–PD PLAN.—The term 'MA–PD plan' has the meaning given such term in section 1860D–41(a)(9) of such Act (42 U.S.C. 1395w–151(a)(9)).

''(D) MEDICARE ADVANTAGE ORGANIZATION.—The term 'Medicare Advantage organization' has the meaning given such term in section 1859(a)(1) of such Act (42 U.S.C. 1395w–28)[sic](a)(1)).

''(E) PDP SPONSOR.—The term 'PDP sponsor' has the meaning given such term in section 1860D–41(a)(13) of such Act (42 U.S.C. 1395w–151(a)(13)).

''(F) PRESCRIPTION DRUG PLAN.—The term 'prescription drug plan' has the meaning given such term in section 1860D–41(a)(14) of such Act (42 U.S.C. 1395w–151(a)(14)).''

SUBMISSION OF LEGISLATIVE PROPOSAL

Pub. L. 108–173, title I, §101(b), Dec. 8, 2003, 117 Stat. 2150, provided that: ''Not later than 6 months after the date of the enactment of this Act [Dec. 8, 2003], the Secretary [of Health and Human Services] shall submit to the appropriate committees of Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this title and title II [see Tables for classification].''

STUDY ON TRANSITIONING PART B PRESCRIPTION DRUG COVERAGE

Pub. L. 108–173, title I, §101(c), Dec. 8, 2003, 117 Stat. 2150, provided that: ''Not later than January 1, 2005, the Secretary [of Health and Human Services] shall submit a report to Congress that makes recommendations regarding methods for providing benefits under subpart 1 of part D of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq.] for outpatient prescription drugs for which benefits are provided under part B of such title [42 U.S.C. 1395j et seq.].''

REPORT ON PROGRESS IN IMPLEMENTATION OF PRESCRIPTION DRUG BENEFIT

Pub. L. 108–173, title I, §101(d), Dec. 8, 2003, 117 Stat. 2150, provided that: ''Not later than March 1, 2005, the Secretary [of Health and Human Services] shall submit a report to Congress on the progress that has been made in implementing the prescription drug benefit 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 [42 U.S.C. 1395w–141] to prescription drug benefits under subpart 1 of part D of title XVIII of such Act [42 U.S.C. 1395w–101 et seq.].''

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 [42 U.S.C. 1395w–101 et seq.], 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 [42 U.S.C. 1395w–114].

''(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 [42 U.S.C. 1395w–101 et seq.], 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, 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)) and access to negotiated prices under subsection (d).

(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) and access to negotiated prices under subsection (d), but only if the benefit design of such coverage is approved by the Secretary, as provided under subsection (c).

(2) Permitting supplemental prescription drug coverage

(A) In general

Subject to subparagraph (B), qualified prescription drug coverage may include supplemental 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, for a year preceding 2025, 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).

(ii) Optional drugs

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

(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, 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.

(5) Construction

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

(b) Standard prescription drug coverage

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

(1) Deductible

(A) In general

Subject to paragraphs (8) and (9), the coverage has an annual deductible—