region under this section shall be for a period of 3 years (except as may be renewed after a subsequent bidding process).

(ii) Limitation

A fallback prescription drug plan may be offered under a contract in an area for a year only if that area is a fallback service area for that year.

(C) Entity not permitted to market or brand fallback prescription drug plans

An eligible fallback entity with a contract under this subsection may not engage in any marketing or branding of a fallback prescription drug plan.

(h) Annual report on use of limited risk plans and fallback plans

The Secretary shall submit to Congress an annual report that describes instances in which limited risk plans and fallback prescription drug plans were offered under subsections (f) and (g). The Secretary shall include in such report such recommendations as may be appropriate to limit the need for the provision of such plans and to maximize the assumption of financial risk under section subsection[3] (f).

(i) Noninterference

In order to promote competition under this part and in carrying out this part, the Secretary—

(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors;

(2) may not require a particular formulary, except as provided under section 1395w–104(b)(3)(*l*)[4] of this title; and

(3) may not institute a price structure for the reimbursement of covered part D drugs, except as provided under part E of subchapter XI.

(j) Coordination of benefits

A PDP sponsor offering a prescription drug plan shall permit State Pharmaceutical Assistance Programs and Rx plans under sections 1395w–133 and 1395w–134 of this title to coordinate benefits with the plan and, in connection with such coordination with such a Program, not to impose fees that are unrelated to the cost of coordination.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D–11, as added Pub. L. 108–173, title I, § 101(a)(2), Dec. 8, 2003, 117 Stat. 2092; amended Pub. L. 111–148, title III, § 3209(b), Mar. 23, 2010, 124 Stat. 460; Pub. L. 117–169, title I, §§ 11001(b)(1)(C), 11201(d)(3)(B), Aug. 16, 2022, 136 Stat. 1852, 1890.)

Editorial Notes

REFERENCES IN TEXT

Section 1395w–115(e)(2)(B)(iii) of this title, referred to in subsec. (b)(2)(E)(ii)(I), was in the original ''section 1869D–15(e)(2)(B)(iii)'', and was translated as reading ''section 1860D–15(e)(2)(B)(iii)'', meaning 1860D–15(e)(2)(B)(iii) of the Social Security Act, to reflect the probable intent of Congress, because the Social Security Act does not contain a section 1869D–15 and section 1395w–115(e)(2)(B)(iii) of this title provides for an application of a higher percentage for years 2006 and 2007.

CODIFICATION

In subsec. (g)(1)(B)(iii), ''section 132 of title 41'' substituted for ''section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5))'' on authority of Pub. L. 111–350, § 6(c), Jan. 4, 2011, 124 Stat. 3854, which Act enacted Title 41, Public Contracts.

AMENDMENTS

2022—Subsec. (g)(6). Pub. L. 117–169, § 11201(d)(3)(B), inserted ''(or, for 2030 and each subsequent year, the percent specified under section 1395w–113(a)(9) of this title)'' after ''25.5 percent''.

Subsec. (i)(1). Pub. L. 117–169, § 11001(b)(1)(C)(i), struck out ''and'' at end.

Subsec. (i)(2). Pub. L. 117–169, § 11001(b)(1)(C)(ii), substituted '', except as provided under section 1395w–104(b)(3)(*l*) of this title; and'' for ''or institute a price structure for the reimbursement of covered part D drugs.''

Subsec. (i)(3). Pub. L. 117–169, § 11001(b)(1)(C)(iii), added par. (3).

2010—Subsec. (d)(3). Pub. L. 111–148 added par. (3).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2010 AMENDMENT

Amendment by Pub. L. 111–148 applicable to bids submitted for contract years beginning on or after Jan. 1, 2011, see section 3209(c) of Pub. L. 111–148, set out as a note under section 1395w–24 of this title.

STUDY REGARDING REGIONAL VARIATIONS IN PRESCRIPTION DRUG SPENDING

Pub. L. 108–173, title I, § 107(a), Dec. 8, 2003, 117 Stat. 2169, provided that:

''(1) IN GENERAL.—The Secretary [of Health and Human Services] shall conduct a study that examines variations in per capita spending for covered part D drugs under part D of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq.] among PDP regions and, with respect to such spending, the amount of such variation that is attributable to—

''(A) price variations (described in section 1860D–15(c)(2) of such Act [42 U.S.C. 1395w–115(c)(2)]); and

''(B) differences in per capita utilization that is not taken into account in the health status risk adjustment provided under section 1860D–15(c)(1) of such Act [42 U.S.C. 1395w–115(c)(1)].

''(2) REPORT AND RECOMMENDATIONS.—Not later than January 1, 2009, the Secretary shall submit to Congress a report on the study conducted under paragraph (1). Such report shall include—

''(A) information regarding the extent of geographic variation described in paragraph (1)(B);

''(B) an analysis of the impact on direct subsidies under section 1860D–15(a)(1) of the Social Security Act [42 U.S.C. 1395w–115(a)(1)] in different PDP regions if such subsidies were adjusted to take into account the variation described in subparagraph (A); and

''(C) recommendations regarding the appropriateness of applying an additional geographic adjustment factor under section 1860D–15(c)(2) [42 U.S.C. 1395w–115(c)(2)] that reflects some or all of the variation described in subparagraph (A).''

§ 1395w–112. Requirements for and contracts with prescription drug plan (PDP) sponsors

(a) General requirements

Each PDP sponsor of a prescription drug plan shall meet the following requirements:

(1) Licensure

Subject to subsection (c), the sponsor is organized and licensed under State law as a risk-

[3] So in original.

[4] So in original. Probably should be ''(b)(3)(I)''.

bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription drug plan.

(2) Assumption of financial risk for unsubsidized coverage

(A) In general

Subject to subparagraph (B), to the extent that the entity is at risk the entity assumes financial risk on a prospective basis for benefits that it offers under a prescription drug plan and that is not covered under section 1395w–115(b) of this title.

(B) Reinsurance permitted

The plan sponsor may obtain insurance or make other arrangements for the cost of coverage provided to any enrollee to the extent that the sponsor is at risk for providing such coverage.

(3) Solvency for unlicensed sponsors

In the case of a PDP sponsor that is not described in paragraph (1) and for which a waiver has been approved under subsection (c), such sponsor shall meet solvency standards established by the Secretary under subsection (d).

(b) Contract requirements

(1) In general

The Secretary shall not permit the enrollment under section 1395w–101 of this title in a prescription drug plan offered by a PDP sponsor under this part, and the sponsor shall not be eligible for payments under section 1395w–114 or 1395w–115 of this title, unless the Secretary has entered into a contract under this subsection with the sponsor with respect to the offering of such plan. Such a contract with a sponsor may cover more than one prescription drug plan. Such contract shall provide that the sponsor agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

(2) Limitation on entities offering fallback prescription drug plans

The Secretary shall not enter into a contract with a PDP sponsor for the offering of a prescription drug plan (other than a fallback prescription drug plan) in a PDP region for a year if the sponsor—

(A) submitted a bid under section 1395w–111(g) of this title for such year (as the first year of a contract period under such section) to offer a fallback prescription drug plan in any PDP region;

(B) offers a fallback prescription drug plan in any PDP region during the year; or

(C) offered a fallback prescription drug plan in that PDP region during the previous year.

For purposes of this paragraph, an entity shall be treated as submitting a bid with respect to a prescription drug plan or offering a fallback prescription drug plan if the entity is acting as a subcontractor of a PDP sponsor that is offering such a plan. The previous sentence shall not apply to entities that are subcontractors of an MA organization except insofar as such organization is acting as a PDP sponsor with respect to a prescription drug plan.

(3) Incorporation of certain medicare advantage contract requirements

Except as otherwise provided, the following provisions of section 1395w–27 of this title shall apply to contracts under this section in the same manner as they apply to contracts under section 1395w–27(a) of this title:

(A) Minimum enrollment

Paragraphs (1) and (3) of section 1395w–27(b) of this title, except that—

(i) the Secretary may increase the minimum number of enrollees required under such paragraph (1) as the Secretary determines appropriate; and

(ii) the requirement of such paragraph (1) shall be waived during the first contract year with respect to an organization in a region.

(B) Contract period and effectiveness

Section 1395w–27(c) of this title, except that in applying paragraph (4)(B) of such section any reference to payment amounts under section 1395w–23 of this title shall be deemed payment amounts under section 1395w–115 of this title.

(C) Protections against fraud and beneficiary protections

Section 1395w–27(d) of this title.

(D) Additional contract terms

Section 1395w–27(e) of this title; except that section 1395w–27(e)(2) of this title shall apply as specified to PDP sponsors and payments under this part to an MA–PD plan shall be treated as expenditures made under part D. Notwithstanding any other provision of law, information provided to the Secretary under the application of section 1395w–27(e)(1) of this title to contracts under this section under the preceding sentence—

(i) may be used for the purposes of carrying out this part, improving public health through research on the utilization, safety, effectiveness, quality, and efficiency of health care services (as the Secretary determines appropriate), or carrying out part E of subchapter XI; and

(ii) shall be made available to Congressional[1] support agencies (in accordance with their obligations to support Congress as set out in their authorizing statutes) for the purposes of conducting Congressional[1] oversight, monitoring, making recommendations, and analysis of the program under this subchapter.

(E) Intermediate sanctions

Section 1395w–27(g) of this title (other than paragraph (1)(F) of such section), except that in applying such section the reference in section 1395w–27(g)(1)(B) of this title to section 1395w–24 of this title is deemed a reference to this part.

(F) Procedures for termination

Section 1395w–27(h) of this title.

[1] So in original. Probably should not be capitalized.

(4) Prompt payment of clean claims

(A) Prompt payment

(i) In general

Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that payment shall be issued, mailed, or otherwise transmitted with respect to all clean claims submitted by pharmacies (other than pharmacies that dispense drugs by mail order only or are located in, or contract with, a long-term care facility) under this part within the applicable number of calendar days after the date on which the claim is received.

(ii) Clean claim defined

In this paragraph, the term ''clean claim'' means a claim that has no defect or impropriety (including any lack of any required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim under this part.

(iii) Date of receipt of claim

In this paragraph, a claim is considered to have been received—

(I) with respect to claims submitted electronically, on the date on which the claim is transferred; and

(II) with respect to claims submitted otherwise, on the 5th day after the postmark date of the claim or the date specified in the time stamp of the transmission.

(B) Applicable number of calendar days defined

In this paragraph, the term ''applicable number of calendar days'' means—

(i) with respect to claims submitted electronically, 14 days; and

(ii) with respect to claims submitted otherwise, 30 days.

(C) Interest payment

(i) In general

Subject to clause (ii), if payment is not issued, mailed, or otherwise transmitted within the applicable number of calendar days (as defined in subparagraph (B)) after a clean claim is received, the PDP sponsor shall pay interest to the pharmacy that submitted the claim at a rate equal to the weighted average of interest on 3-month marketable Treasury securities determined for such period, increased by 0.1 percentage point for the period beginning on the day after the required payment date and ending on the date on which payment is made (as determined under subparagraph (D)(iv)). Interest amounts paid under this subparagraph shall not be counted against the administrative costs of a prescription drug plan or treated as allowable risk corridor costs under section 1395w–115(e) of this title.

(ii) Authority not to charge interest

The Secretary may provide that a PDP sponsor is not charged interest under clause (i) in the case where there are exigent circumstances, including natural disasters and other unique and unexpected events, that prevent the timely processing of claims.

(D) Procedures involving claims

(i) Claim deemed to be clean

A claim is deemed to be a clean claim if the PDP sponsor involved does not provide notice to the claimant of any deficiency in the claim—

(I) with respect to claims submitted electronically, within 10 days after the date on which the claim is received; and

(II) with respect to claims submitted otherwise, within 15 days after the date on which the claim is received.

(ii) Claim determined to not be a clean claim

(I) In general

If a PDP sponsor determines that a submitted claim is not a clean claim, the PDP sponsor shall, not later than the end of the period described in clause (i), notify the claimant of such determination. Such notification shall specify all defects or improprieties in the claim and shall list all additional information or documents necessary for the proper processing and payment of the claim.

(II) Determination after submission of additional information

A claim is deemed to be a clean claim under this paragraph if the PDP sponsor involved does not provide notice to the claimant of any defect or impropriety in the claim within 10 days of the date on which additional information is received under subclause (I).

(iii) Obligation to pay

A claim submitted to a PDP sponsor that is not paid or contested by the sponsor within the applicable number of days (as defined in subparagraph (B)) after the date on which the claim is received shall be deemed to be a clean claim and shall be paid by the PDP sponsor in accordance with subparagraph (A).

(iv) Date of payment of claim

Payment of a clean claim under such subparagraph is considered to have been made on the date on which—

(I) with respect to claims paid electronically, the payment is transferred; and

(II) with respect to claims paid otherwise, the payment is submitted to the United States Postal Service or common carrier for delivery.

(E) Electronic transfer of funds

A PDP sponsor shall pay all clean claims submitted electronically by electronic transfer of funds if the pharmacy so requests or has so requested previously. In the case where such payment is made electronically, remittance may be made by the PDP sponsor electronically as well.

(F) Protecting the rights of claimants

(i) In general

Nothing in this paragraph shall be construed to prohibit or limit a claim or action not covered by the subject matter of this section that any individual or organization has against a provider or a PDP sponsor.

(ii) Anti-retaliation

Consistent with applicable Federal or State law, a PDP sponsor shall not retaliate against an individual or provider for exercising a right of action under this subparagraph.

(G) Rule of construction

A determination under this paragraph that a claim submitted by a pharmacy is a clean claim shall not be construed as a positive determination regarding eligibility for payment under this subchapter, nor is it an indication of government approval of, or acquiescence regarding, the claim submitted. The determination shall not relieve any party of civil or criminal liability with respect to the claim, nor does it offer a defense to any administrative, civil, or criminal action with respect to the claim.

(5) Submission of claims by pharmacies located in or contracting with long-term care facilities

Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that a pharmacy located in, or having a contract with, a long-term care facility shall have not less than 30 days (but not more than 90 days) to submit claims to the sponsor for reimbursement under the plan.

(6) Regular update of prescription drug pricing standard

If the PDP sponsor of a prescription drug plan uses a standard for reimbursement of pharmacies based on the cost of a drug, each contract entered into with such sponsor under this part with respect to the plan shall provide that the sponsor shall update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug.

(7) Suspension of payments pending investigation of credible allegations of fraud by pharmacies

(A) In general

Section 1395y(*o*)(1) of this title shall apply with respect to a PDP sponsor with a contract under this part, a pharmacy, and payments to such pharmacy under this part in the same manner as such section applies with respect to the Secretary, a provider of services or supplier, and payments to such provider of services or supplier under this subchapter. A PDP sponsor shall notify the Secretary regarding the imposition of any payment suspension pursuant to the previous sentence, such as through the secure internet website portal (or other successor technology) established under section 1395w–28(i) of this title.

(B) Rule of construction

Nothing in this paragraph shall be construed as limiting the authority of a PDP sponsor to conduct postpayment review.

(8) Provision of information related to maximum fair prices

Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall require the sponsor to provide information to the Secretary as requested by the Secretary for purposes of carrying out section 1320f–3 of this title.

(c) Waiver of certain requirements to expand choice

(1) Authorizing waiver

(A) In general

In the case of an entity that seeks to offer a prescription drug plan in a State, the Secretary shall waive the requirement of subsection (a)(1) that the entity be licensed in that State if the Secretary determines, based on the application and other evidence presented to the Secretary, that any of the grounds for approval of the application described in paragraph (2) have been met.

(B) Application of regional plan waiver rule

In addition to the waiver available under subparagraph (A), the provisions of section 1395w–27a(d) of this title shall apply to PDP sponsors under this part in a manner similar to the manner in which such provisions apply to MA organizations under part C, except that no application shall be required under paragraph (1)(B) of such section in the case of a State that does not provide a licensing process for such a sponsor.

(2) Grounds for approval

(A) In general

The grounds for approval under this paragraph are—

(i) subject to subparagraph (B), the grounds for approval described in subparagraphs (B), (C), and (D) of section 1395w–25(a)(2) of this title; and

(ii) the application by a State of any grounds other than those required under Federal law.

(B) Special rules

In applying subparagraph (A)(i)—

(i) the ground of approval described in section 1395w–25(a)(2)(B) of this title is deemed to have been met if the State does not have a licensing process in effect with respect to the PDP sponsor; and

(ii) for plan years beginning before January 1, 2008, if the State does have such a licensing process in effect, such ground for approval described in such section is deemed to have been met upon submission of an application described in such section.

(3) Application of waiver procedures

With respect to an application for a waiver (or a waiver granted) under paragraph (1)(A) of

this subsection, the provisions of subparagraphs (E), (F), and (G) of section 1395w–25(a)(2) of this title shall apply, except that clauses (i) and (ii) of such subparagraph (E) shall not apply in the case of a State that does not have a licensing process described in paragraph (2)(B)(i) in effect.

(4) References to certain provisions

In applying provisions of section 1395w–25(a)(2) of this title under paragraphs (2) and (3) of this subsection to prescription drug plans and PDP sponsors—

(A) any reference to a waiver application under section 1395w–25 of this title shall be treated as a reference to a waiver application under paragraph (1)(A) of this subsection; and

(B) any reference to solvency standards shall be treated as a reference to solvency standards established under subsection (d) of this section.

(d) Solvency standards for non-licensed entities

(1) Establishment and publication

The Secretary, in consultation with the National Association of Insurance Commissioners, shall establish and publish, by not later than January 1, 2005, financial solvency and capital adequacy standards for entities described in paragraph (2).

(2) Compliance with standards

A PDP sponsor that is not licensed by a State under subsection (a)(1) and for which a waiver application has been approved under subsection (c) shall meet solvency and capital adequacy standards established under paragraph (1). The Secretary shall establish certification procedures for such sponsors with respect to such solvency standards in the manner described in section 1395w–25(c)(2) of this title.

(e) Licensure does not substitute for or constitute certification

The fact that a PDP sponsor is licensed in accordance with subsection (a)(1) or has a waiver application approved under subsection (c) does not deem the sponsor to meet other requirements imposed under this part for a sponsor.

(f) Periodic review and revision of standards

(1) In general

Subject to paragraph (2), the Secretary may periodically review the standards established under this section and, based on such review, may revise such standards if the Secretary determines such revision to be appropriate.

(2) Prohibition of midyear implementation of significant new regulatory requirements

The Secretary may not implement, other than at the beginning of a calendar year, regulations under this section that impose new, significant regulatory requirements on a PDP sponsor or a prescription drug plan.

(g) Prohibition of State imposition of premium taxes; relation to State laws

The provisions of sections 1395w–24(g) and 1395w–26(b)(3) of this title shall apply with respect to PDP sponsors and prescription drug plans under this part in the same manner as such sections apply to MA organizations and MA plans under part C.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D–12, as added Pub. L. 108–173, title I, § 101(a)(2), Dec. 8, 2003, 117 Stat. 2099; amended Pub. L. 110–275, title I, §§ 171(a), 172(a)(1), 173(a), 181, July 15, 2008, 122 Stat. 2578, 2580–2582; Pub. L. 115–271, title II, § 2008(a), Oct. 24, 2018, 132 Stat. 3931; Pub. L. 117–169, title I, § 11001(b)(1)(F)(i), (H)(i), Aug. 16, 2022, 136 Stat. 1852, 1853.)

Editorial Notes

AMENDMENTS

2022—Subsec. (b)(3)(D)(i). Pub. L. 117–169, § 11001(b)(1)(H)(i), inserted '', or carrying out part E of subchapter XI'' after ''appropriate)''.

Subsec. (b)(8). Pub. L. 117–169, § 11001(b)(1)(F)(i), added par. (8).

2018—Subsec. (b)(7). Pub. L. 115–271 added par. (7).

2008—Subsec. (b)(3)(D). Pub. L. 110–275, § 181, inserted at end ''Notwithstanding any other provision of law, information provided to the Secretary under the application of section 1395w–27(e)(1) of this title to contracts under this section under the preceding sentence—'' and added cls. (i) and (ii).

Subsec. (b)(4). Pub. L. 110–275, § 171(a), added par. (4).

Subsec. (b)(5). Pub. L. 110–275, § 172(a)(1), added par. (5).

Subsec. (b)(6). Pub. L. 110–275, § 173(a), added par. (6).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2018 AMENDMENT

Amendment by section 2008(a) of Pub. L. 115–271 applicable with respect to plan years beginning on or after Jan. 1, 2020, see section 2008(e) of Pub. L. 115–271, set out as a note under section 1395w–27 of this title.

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 171(a) of Pub. L. 110–275 applicable to plan years beginning on or after Jan. 1, 2010, see section 171(c) of Pub. L. 110–275, set out as a note under section 1395w–27 of this title.

Amendment by section 172(a)(1) of Pub. L. 110–275 applicable to plan years beginning on or after Jan. 1, 2010, see section 172(b) of Pub. L. 110–275, set out as a note under section 1395w–27 of this title.

Amendment by section 173(a) of Pub. L. 110–275 applicable to plan years beginning on or after Jan. 1, 2009, see section 173(c) of Pub. L. 110–275, set out as a note under section 1395w–27 of this title.

§ 1395w–113. Premiums; late enrollment penalty

(a) Monthly beneficiary premium

(1) Computation

(A) In general

The monthly beneficiary premium for a prescription drug plan is the base beneficiary premium computed under paragraph (2) or (8) (as applicable) as adjusted under this paragraph.

(B) Adjustment to reflect difference between bid and national average bid

(i) Above average bid

If for a month the amount of the standardized bid amount (as defined in paragraph (5)) exceeds the amount of the adjusted national average monthly bid amount (as defined in clause (iii)), the base beneficiary premium for the month shall be increased by the amount of such excess.