

“(2) USE OF GRANT FUNDS.—Funds provided under grants under this section may be used for any of the following:

“(A) For purchasing, leasing, and installing computer software and hardware, including handheld computer technologies.

“(B) Making upgrades and other improvements to existing computer software and hardware to enable e-prescribing.

“(C) Providing education and training to eligible physician staff on the use of technology to implement the electronic transmission of prescription and patient information.

“(3) PROVISION OF INFORMATION.—As a condition for the awarding of a grant under this section, an applicant shall provide to the Secretary such information as the Secretary may require in order to—

“(A) evaluate the project for which the grant is made; and

“(B) ensure that funding provided under the grant is expended only for the purposes for which it is made.

“(4) AUDIT.—The Secretary shall conduct appropriate audits of grants under this section.

“(5) MATCHING REQUIREMENT.—The applicant for a grant under this section shall agree, with respect to the costs to be incurred by the applicant in implementing an electronic prescription drug program, to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 50 percent of such costs. Non-Federal contributions under the previous sentence may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

“(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section \$50,000,000 for fiscal year 2007 and such sums as may be necessary for each of fiscal years 2008 and 2009.”

SUBPART 2—PRESCRIPTION DRUG PLANS; PDP SPONSORS; FINANCING

**§ 1395w-111. PDP regions; submission of bids; plan approval**

**(a) Establishment of PDP regions; service areas**

**(1) Coverage of entire PDP region**

The service area for a prescription drug plan shall consist of an entire PDP region established under paragraph (2).

**(2) Establishment of PDP regions**

**(A) In general**

The Secretary shall establish, and may revise, PDP regions in a manner that is consistent with the requirements for the establishment and revision of MA regions under subparagraphs (B) and (C) of section 1395w-27a(a)(2) of this title.

**(B) Relation to MA regions**

To the extent practicable, PDP regions shall be the same as MA regions under section 1395w-27a(a)(2) of this title. The Secretary may establish PDP regions which are not the same as MA regions if the Secretary determines that the establishment of different regions under this part would improve access to benefits under this part.

**(C) Authority for territories**

The Secretary shall establish, and may revise, PDP regions for areas in States that

are not within the 50 States or the District of Columbia.

**(3) National plan**

Nothing in this subsection shall be construed as preventing a prescription drug plan from being offered in more than one PDP region (including all PDP regions).

**(b) Submission of bids, premiums, and related information**

**(1) In general**

A PDP sponsor shall submit to the Secretary information described in paragraph (2) with respect to each prescription drug plan it offers. Such information shall be submitted at the same time and in a similar manner to the manner in which information described in paragraph (6) of section 1395w-24(a) of this title is submitted by an MA organization under paragraph (1) of such section.

**(2) Information described**

The information described in this paragraph is information on the following:

**(A) Coverage provided**

The prescription drug coverage provided under the plan, including the deductible and other cost-sharing.

**(B) Actuarial value**

The actuarial value of the qualified prescription drug coverage in the region for a part D eligible individual with a national average risk profile for the factors described in section 1395w-115(c)(1)(A) of this title (as specified by the Secretary).

**(C) Bid**

Information on the bid, including an actuarial certification of—

(i) the basis for the actuarial value described in subparagraph (B) assumed in such bid;

(ii) the portion of such bid attributable to basic prescription drug coverage and, if applicable, the portion of such bid attributable to supplemental benefits;

(iii) assumptions regarding the reinsurance subsidy payments provided under section 1395w-115(b) of this title subtracted from the actuarial value to produce such bid; and

(iv) administrative expenses assumed in the bid.

**(D) Service area**

The service area for the plan.

**(E) Level of risk assumed**

**(i) In general**

Whether the PDP sponsor requires a modification of risk level under clause (ii) and, if so, the extent of such modification. Any such modification shall apply with respect to all prescription drug plans offered by a PDP sponsor in a PDP region. This subparagraph shall not apply to an MA-PD plan.

**(ii) Risk levels described**

A modification of risk level under this clause may consist of one or more of the following:

**(I) Increase in Federal percentage assumed in initial risk corridor**

An equal percentage point increase in the percents applied under subparagraphs (B)(i), (B)(ii)(I), (C)(i), and (C)(ii)(I) of section 1395w-115(e)(2) of this title. In no case shall the application of previous sentence prevent the application of a higher percentage under section 1395w-115(e)(2)(B)(iii)<sup>1</sup> of this title.

**(II) Increase in Federal percentage assumed in second risk corridor**

An equal percentage point increase in the percents applied under subparagraphs (B)(ii)(II) and (C)(ii)(II) of section 1395w-115(e)(2) of this title.

**(III) Decrease in size of risk corridors**

A decrease in the threshold risk percentages specified in section 1395w-115(e)(3)(C) of this title.

**(F) Additional information**

Such other information as the Secretary may require to carry out this part.

**(3) Paperwork reduction for offering of prescription drug plans nationally or in multi-region areas**

The Secretary shall establish requirements for information submission under this subsection in a manner that promotes the offering of such plans in more than one PDP region (including all regions) through the filing of consolidated information.

**(c) Actuarial valuation****(1) Processes**

For purposes of this part, the Secretary shall establish processes and methods for determining the actuarial valuation of prescription drug coverage, including—

(A) an actuarial valuation of standard prescription drug coverage under section 1395w-102(b) of this title;

(B) actuarial valuations relating to alternative prescription drug coverage under section 1395w-102(c)(1) of this title;

(C) an actuarial valuation of the reinsurance subsidy payments under section 1395w-115(b) of this title;

(D) the use of generally accepted actuarial principles and methodologies; and

(E) applying the same methodology for determinations of actuarial valuations under subparagraphs (A) and (B).

**(2) Accounting for drug utilization**

Such processes and methods for determining actuarial valuation shall take into account the effect that providing alternative prescription drug coverage (rather than standard prescription drug coverage) has on drug utilization.

**(3) Responsibilities****(A) Plan responsibilities**

PDP sponsors and MA organizations are responsible for the preparation and submission

of actuarial valuations required under this part for prescription drug plans and MA-PD plans they offer.

**(B) Use of outside actuaries**

Under the processes and methods established under paragraph (1), PDP sponsors offering prescription drug plans and MA organizations offering MA-PD plans may use actuarial opinions certified by independent, qualified actuaries to establish actuarial values.

**(d) Review of information and negotiation****(1) Review of information**

The Secretary shall review the information filed under subsection (b) for the purpose of conducting negotiations under paragraph (2).

**(2) Negotiation regarding terms and conditions**

Subject to subsection (i), in exercising the authority under paragraph (1), the Secretary—

(A) has the authority to negotiate the terms and conditions of the proposed bid submitted and other terms and conditions of a proposed plan; and

(B) has authority similar to the authority of the Director of the Office of Personnel Management with respect to health benefits plans under chapter 89 of title 5.

**(3) Rejection of bids**

Paragraph (5)(C) of section 1395w-24(a) of this title shall apply with respect to bids submitted by a PDP sponsor under subsection (b) in the same manner as such paragraph applies to bids submitted by an MA organization under such section 1395w-24(a) of this title.

**(e) Approval of proposed plans****(1) In general**

After review and negotiation under subsection (d), the Secretary shall approve or disapprove the prescription drug plan.

**(2) Requirements for approval**

The Secretary may approve a prescription drug plan only if the following requirements are met:

**(A) Compliance with requirements**

The plan and the PDP sponsor offering the plan comply with the requirements under this part, including the provision of qualified prescription drug coverage.

**(B) Actuarial determinations**

The Secretary determines that the plan and PDP sponsor meet the requirements under this part relating to actuarial determinations, including such requirements under section 1395w-102(c) of this title.

**(C) Application of FEHBP standard****(i) In general**

The Secretary determines that the portion of the bid submitted under subsection (b) that is attributable to basic prescription drug coverage is supported by the actuarial bases provided under such subsection and reasonably and equitably reflects the revenue requirements (as used for purposes of section 300e-1(8)(C) of this

<sup>1</sup> See References in Text note below.

title) for benefits provided under that plan, less the sum (determined on a monthly per capita basis) of the actuarial value of the reinsurance payments under section 1395w-115(b) of this title.

**(ii) Supplemental coverage**

The Secretary determines that the portion of the bid submitted under subsection (b) that is attributable to supplemental prescription drug coverage pursuant to section 1395w-102(a)(2) of this title is supported by the actuarial bases provided under such subsection and reasonably and equitably reflects the revenue requirements (as used for purposes of section 300e-1(8)(C) of this title) for such coverage under the plan.

**(D) Plan design**

**(i) In general**

The Secretary does not find that the design of the plan and its benefits (including any formulary and tiered formulary structure) are likely to substantially discourage enrollment by certain part D eligible individuals under the plan.

**(ii) Use of categories and classes in formularies**

The Secretary may not find that the design of categories and classes within a formulary violates clause (i) if such categories and classes are consistent with guidelines (if any) for such categories and classes established by the United States Pharmacopeia.

**(f) Application of limited risk plans**

**(1) Conditions for approval of limited risk plans**

The Secretary may only approve a limited risk plan (as defined in paragraph (4)(A)) for a PDP region if the access requirements under section 1395w-103(a) of this title would not be met for the region but for the approval of such a plan (or a fallback prescription drug plan under subsection (g)).

**(2) Rules**

The following rules shall apply with respect to the approval of a limited risk plan in a PDP region:

**(A) Limited exercise of authority**

Only the minimum number of such plans may be approved in order to meet the access requirements under section 1395w-103(a) of this title.

**(B) Maximizing assumption of risk**

The Secretary shall provide priority in approval for those plans bearing the highest level of risk (as computed by the Secretary), but the Secretary may take into account the level of the bids submitted by such plans.

**(C) No full underwriting for limited risk plans**

In no case may the Secretary approve a limited risk plan under which the modification of risk level provides for no (or a de minimis) level of financial risk.

**(3) Acceptance of all full risk contracts**

There shall be no limit on the number of full risk plans that are approved under subsection (e).

**(4) Risk-plans defined**

For purposes of this subsection:

**(A) Limited risk plan**

The term “limited risk plan” means a prescription drug plan that provides basic prescription drug coverage and for which the PDP sponsor includes a modification of risk level described in subparagraph (E) of subsection (b)(2) in its bid submitted for the plan under such subsection. Such term does not include a fallback prescription drug plan.

**(B) Full risk plan**

The term “full risk plan” means a prescription drug plan that is not a limited risk plan or a fallback prescription drug plan.

**(g) Guaranteeing access to coverage**

**(1) Solicitation of bids**

**(A) In general**

Separate from the bidding process under subsection (b), the Secretary shall provide for a process for the solicitation of bids from eligible fallback entities (as defined in paragraph (2)) for the offering in all fallback service areas (as defined in paragraph (3)) in one or more PDP regions of a fallback prescription drug plan (as defined in paragraph (4)) during the contract period specified in paragraph (5).

**(B) Acceptance of bids**

**(i) In general**

Except as provided in this subparagraph, the provisions of subsection (e) shall apply with respect to the approval or disapproval of fallback prescription drug plans. The Secretary shall enter into contracts under this subsection with eligible fallback entities for the offering of fallback prescription drug plans so approved in fallback service areas.

**(ii) Limitation of 1 plan for all fallback service areas in a PDP region**

With respect to all fallback service areas in any PDP region for a contract period, the Secretary shall approve the offering of only 1 fallback prescription drug plan.

**(iii) Competitive procedures**

Competitive procedures (as defined in section 132 of title 41) shall be used to enter into a contract under this subsection. The provisions of subsection (d) of section 1395kk-1 of this title shall apply to a contract under this section in the same manner as they apply to a contract under such section.

**(iv) Timing**

The Secretary shall approve a fallback prescription drug plan for a PDP region in a manner so that, if there are any fallback service areas in the region for a year, the

fallback prescription drug plan is offered at the same time as prescription drug plans would otherwise be offered.

**(V)<sup>2</sup> No national fallback plan**

The Secretary shall not enter into a contract with a single fallback entity for the offering of fallback plans throughout the United States.

**(2) Eligible fallback entity**

For purposes of this section, the term “eligible fallback entity” means, with respect to all fallback service areas in a PDP region for a contract period, an entity that—

(A) meets the requirements to be a PDP sponsor (or would meet such requirements but for the fact that the entity is not a risk-bearing entity); and

(B) does not submit a bid under subsection (b) for any prescription drug plan for any PDP region for the first year of such contract period.

For purposes of subparagraph (B), an entity shall be treated as submitting a bid with respect to a 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) Fallback service area**

For purposes of this subsection, the term “fallback service area” means, for a PDP region with respect to a year, any area within such region for which the Secretary determines before the beginning of the year that the access requirements of the first sentence of section 1395w-103(a) of this title will not be met for part D eligible individuals residing in the area for the year.

**(4) Fallback prescription drug plan**

For purposes of this part, the term “fallback prescription drug plan” means a prescription drug plan that—

(A) only offers the standard prescription drug coverage and access to negotiated prices described in section 1395w-102(a)(1)(A) of this title and does not include any supplemental prescription drug coverage; and

(B) meets such other requirements as the Secretary may specify.

**(5) Payments under the contract**

**(A) In general**

A contract entered into under this subsection shall provide for—

(i) payment for the actual costs (taking into account negotiated price concessions described in section 1395w-102(d)(1)(B) of this title) of covered part D drugs provided to part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity; and

(ii) payment of management fees that are tied to performance measures estab-

lished by the Secretary for the management, administration, and delivery of the benefits under the contract.

**(B) Performance measures**

The performance measures established by the Secretary pursuant to subparagraph (A)(ii) shall include at least measures for each of the following:

**(i) Costs**

The entity contains costs to the Medicare Prescription Drug Account and to part D eligible individuals enrolled in a fallback prescription drug plan offered by the entity through mechanisms such as generic substitution and price discounts.

**(ii) Quality programs**

The entity provides such enrollees with quality programs that avoid adverse drug reactions and overutilization and reduce medical errors.

**(iii) Customer service**

The entity provides timely and accurate delivery of services and pharmacy and beneficiary support services.

**(iv) Benefit administration and claims adjudication**

The entity provides efficient and effective benefit administration and claims adjudication.

**(6) Monthly beneficiary premium**

Except as provided in section 1395w-113(b) of this title (relating to late enrollment penalty) and subject to section 1395w-114 of this title (relating to low-income assistance), the monthly beneficiary premium to be charged under a fallback prescription drug plan offered in all fallback service areas in a PDP region shall be uniform and shall be equal to 25.5 percent (or, for 2030 and each subsequent year, the percent specified under section 1395w-113(a)(9) of this title) of an amount equal to the Secretary’s estimate of the average monthly per capita actuarial cost, including administrative expenses, under the fallback prescription drug plan of providing coverage in the region, as calculated by the Chief Actuary of the Centers for Medicare & Medicaid Services. In calculating such administrative expenses, the Chief Actuary shall use a factor that is based on similar expenses of prescription drug plans that are not fallback prescription drug plans.

**(7) General contract terms and conditions**

**(A) In general**

Except as may be appropriate to carry out this section, the terms and conditions of contracts with eligible fallback entities offering fallback prescription drug plans under this subsection shall be the same as the terms and conditions of contracts under this part for prescription drug plans.

**(B) Period of contract**

**(i) In general**

Subject to clause (ii), a contract approved for a fallback prescription drug plan for fallback service areas for a PDP

<sup>2</sup>So in original. Probably should be “(v)”.

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<sup>3</sup> (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)(I)<sup>4</sup> 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

<sup>3</sup>So in original.

<sup>4</sup>So in original. Probably should be “(b)(3)(I)”.

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)(I) 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-