

111TH CONGRESS
2^D SESSION

S. 4024

To reduce the costs of prescription drugs for Medicare beneficiaries and to guarantee access to comprehensive prescription drug coverage under part D of the Medicare program, and for other purposes.

IN THE SENATE OF THE UNITED STATES

DECEMBER 10, 2010

Mr. WYDEN (for himself and Ms. SNOWE) introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To reduce the costs of prescription drugs for Medicare beneficiaries and to guarantee access to comprehensive prescription drug coverage under part D of the Medicare program, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medicare Enhance-
5 ments for Needed Drugs Act of 2010”.

1 **SEC. 2. GAO STUDIES AND REPORTS ON PRICES OF PRE-**
2 **SCRIPTION DRUGS.**

3 (a) REVIEW AND REPORTS ON RETAIL PRICES OF
4 PRESCRIPTION DRUGS.—

5 (1) INITIAL REVIEW.—The Comptroller General
6 of the United States shall conduct a review of the
7 retail cost of prescription drugs in the United States
8 during 2004 through 2010, with an emphasis on the
9 prescription drugs most utilized for individuals age
10 65 or older.

11 (2) SUBSEQUENT REVIEW.—After conducting
12 the review under paragraph (1), the Comptroller
13 General shall continuously review the retail cost of
14 such drugs through December 31, 2014, to deter-
15 mine the changes in such costs.

16 (3) REPORTS.—

17 (A) INITIAL REVIEW.—Not later than 90
18 days after the date of enactment of this Act,
19 the Comptroller General shall submit to Con-
20 gress a report on the initial review conducted
21 under paragraph (1).

22 (B) SUBSEQUENT REVIEW.—Not later
23 than April 1 of 2012, 2013, 2014, and 2015,
24 the Comptroller General shall submit to Con-
25 gress a report on the subsequent review con-
26 ducted under paragraph (2).

1 (b) ANNUAL GAO STUDY AND REPORT ON RETAIL
2 AND ACQUISITION PRICES OF CERTAIN PRESCRIPTION
3 DRUGS.—

4 (1) ONGOING STUDY.—The Comptroller Gen-
5 eral of the United States shall conduct an ongoing
6 study that compares the average retail cost in the
7 United States for each of the 20 most utilized pre-
8 scription drugs for individuals age 65 or older
9 with—

10 (A) the average price at which private
11 health plans acquire each such drug;

12 (B) the average price at which the Depart-
13 ment of Defense under the Defense Health Pro-
14 gram acquires each such drug;

15 (C) the average price at which the Depart-
16 ment of Veterans Affairs under the laws admin-
17 istered by the Secretary of Veterans Affairs ac-
18 quires each such drug; and

19 (D) the average negotiated price for each
20 such drug that eligible beneficiaries enrolled in
21 a prescription drug plan under part D of title
22 XVIII of the Social Security Act that provides
23 only basic prescription drug coverage have ac-
24 cess to under such plans.

1 (2) ANNUAL REPORT.—Not later than October
 2 1, 2011, and annually thereafter, the Comptroller
 3 General shall submit to Congress a report on the
 4 study conducted under paragraph (1), together with
 5 such recommendations as the Comptroller General
 6 determines appropriate.

7 **SEC. 3. INCLUSION OF AVERAGE AGGREGATE BENEFICIARY**
 8 **COSTS AND SAVINGS IN COMPARATIVE IN-**
 9 **FORMATION FOR BASIC MEDICARE PRE-**
 10 **SCRIPTION DRUG PLANS.**

11 Section 1860D–1(c)(3) of the Social Security Act (42
 12 U.S.C. 1395w–101(c)(3)) is amended—

13 (1) in subparagraph (A)—

14 (A) in the matter preceding clause (i), by
 15 striking “subparagraph (B)” and inserting
 16 “subparagraphs (B) and (C)”; and

17 (B) by adding at the end the following new
 18 clause:

19 “(vi) AVERAGE AGGREGATE BENE-
 20 FICIARY COSTS AND SAVINGS.—With re-
 21 spect to plan years beginning on or after
 22 January 1, 2012, the average aggregate
 23 costs, including deductibles and other cost-
 24 sharing, that a beneficiary will incur for
 25 covered part D drugs in the year under the

1 plan compared to the average aggregate
 2 costs that an eligible beneficiary with no
 3 prescription drug coverage will incur for
 4 covered part D drugs in the year.”; and

5 (2) by adding at the end the following new sub-
 6 paragraph:

7 “(C) AVERAGE AGGREGATE BENEFICIARY
 8 COSTS AND SAVINGS INFORMATION ONLY FOR
 9 BASIC PRESCRIPTION DRUG PLANS.—The Sec-
 10 retary shall not provide comparative informa-
 11 tion under subparagraph (A)(vi) with respect
 12 to—

13 “(i) a prescription drug plan that pro-
 14 vides supplemental prescription drug cov-
 15 erage; or

16 “(ii) a Medicare Advantage plan.”.

17 **SEC. 4. NEGOTIATING FAIR PRICES FOR MEDICARE PRE-**
 18 **SCRIPTION DRUGS.**

19 (a) IN GENERAL.—Section 1860D–11 of the Social
 20 Security Act (42 U.S.C. 1395w–111) is amended by strik-
 21 ing subsection (i) (relating to noninterference) and by in-
 22 serting the following:

23 “(i) AUTHORITY TO NEGOTIATE PRICES WITH MAN-
 24 UFACTURERS.—

1 “(1) IN GENERAL.—In order to ensure that
2 beneficiaries enrolled under prescription drug plans
3 and MA–PD plans pay the lowest possible price, the
4 Secretary shall have authority similar to that of
5 other Federal entities that purchase prescription
6 drugs in bulk to negotiate contracts with manufac-
7 turers of covered part D drugs, consistent with the
8 requirements and in furtherance of the goals of pro-
9 viding quality care and containing costs under this
10 part.

11 “(2) MANDATORY RESPONSIBILITIES.—The
12 Secretary shall be required to—

13 “(A) negotiate contracts with manufactur-
14 ers of covered part D drugs when the drug is
15 a single source drug without a therapeutic
16 equivalent;

17 “(B) participate in the negotiation of con-
18 tracts with respect to any covered part D drug
19 upon the request of an approved prescription
20 drug plan or MA–PD plan;

21 “(C) participate in the negotiation of con-
22 tracts for any covered part D drugs for which
23 there is a substantial amount of Federal re-
24 search funding in the development of the drug;
25 and

1 “(D) negotiate contracts with manufactur-
2 ers of covered part D drugs for each standard
3 fallback prescription drug plan under subsection
4 (g) and each comprehensive fallback prescrip-
5 tion drug plan under subsection (k).

6 “(3) RULE OF CONSTRUCTION.—Nothing in
7 paragraph (2) shall be construed to limit the author-
8 ity of the Secretary under paragraph (1) to the man-
9 datory responsibilities under paragraph (2).

10 “(4) NO PARTICULAR FORMULARY OR PRICE
11 STRUCTURE.—In order to promote competition
12 under this part and in carrying out this part, the
13 Secretary may not require a particular formulary or
14 institute a price structure for the reimbursement of
15 covered part D drugs.

16 “(5) USE OF SAVINGS.—The savings to the
17 Medicare Prescription Drug Account through the
18 use of the authority provided under this subsection
19 (including the mandatory responsibilities under
20 paragraph (2)) shall be used to strengthen the pro-
21 gram under this part and to reduce the Federal def-
22 icit.”.

23 (b) EFFECTIVE DATE.—The amendment made by
24 this section shall take effect on the date of enactment of
25 this Act.

1 **SEC. 5. ACCESS TO A COMPREHENSIVE MEDICARE PRE-**
 2 **SCRIPTION DRUG PLAN.**

3 (a) REQUIREMENT FOR ACCESS.—Section 1860D–
 4 3(a) of the Social Security Act (42 U.S.C. 1395w–103(a))
 5 is amended—

6 (1) in paragraph (1)—

7 (A) by striking “CHOICE OF AT LEAST
 8 TWO PLANS IN EACH AREA.—The Secretary”
 9 and inserting “CHOICE.—

10 “(A) CHOICE OF AT LEAST TWO PLANS IN
 11 EACH AREA.—The Secretary”; and

12 (B) by adding at the end the following new
 13 subparagraph:

14 “(B) CHOICE OF A COMPREHENSIVE PRE-
 15 SCRIPTON DRUG PLAN.—In addition to the re-
 16 quirement under subparagraph (A), the Sec-
 17 retary shall ensure that each part D eligible in-
 18 dividual has available a choice of enrollment in
 19 a comprehensive prescription drug plan (as de-
 20 fined in paragraph (4)) in the area in which the
 21 individual resides. In any such case in which
 22 such a plan is not available, the part D eligible
 23 individual shall be given the opportunity to en-
 24 roll in a comprehensive fallback prescription
 25 drug plan.”; and

1 (2) by adding at the end the following new
2 paragraph:

3 “(4) COMPREHENSIVE PRESCRIPTION DRUG
4 PLAN.—For purposes of this section, the term ‘com-
5 prehensive prescription drug plan’ means a prescrip-
6 tion drug plan that provides coverage of covered part
7 D drugs after an individual has reached the initial
8 coverage limit under paragraph (3) of section
9 1860D–2(b) but has not reached the annual out-of-
10 pocket threshold under paragraph (4)(B) of such
11 section that is the same as the coverage for such
12 drugs that is provided under the plan after the indi-
13 vidual has met the deductible under paragraph (1)
14 of such section but has not reached such initial cov-
15 erage limit.”.

16 (b) COMPREHENSIVE FALLBACK PRESCRIPTION
17 DRUG PLAN.—Section 1860D–11 of the Social Security
18 Act (42 U.S.C. 1395w–111) is amended by adding at the
19 end the following new subsection:

20 “(k) GUARANTEEING ACCESS TO COMPREHENSIVE
21 COVERAGE.—

22 “(1) SOLICITATION OF BIDS.—Separate from
23 the bidding process under subsections (b) and (g),
24 the Secretary shall provide for a process for the so-
25 licitation of bids from eligible comprehensive fallback

1 entities (as defined in paragraph (2)) for the offer-
2 ing in all comprehensive fallback service areas (as
3 defined in paragraph (3)) in one or more PDP re-
4 gions of a comprehensive fallback prescription drug
5 plan (as defined in paragraph (4)) during the con-
6 tract period specified in subsection (g)(5) (as made
7 applicable to this subsection under paragraph (6)).

8 “(2) ELIGIBLE COMPREHENSIVE FALLBACK EN-
9 TITY.—For purposes of this section, the term ‘eligi-
10 ble comprehensive fallback entity’ means, with re-
11 spect to all comprehensive fallback service areas in
12 a PDP region for a contract period, an entity that—

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

17 “(B) does not submit a bid under section
18 1860D–11(b) for any prescription drug plan for
19 any PDP region for the first year of such con-
20 tract period.

21 For purposes of subparagraph (B), an entity shall
22 be treated as submitting a bid with respect to a pre-
23 scription drug plan if the entity is acting as a sub-
24 contractor of a PDP sponsor that is offering such a
25 plan. The previous sentence shall not apply to enti-

1 ties that are subcontractors of an MA organization
2 except insofar as such organization is acting as a
3 PDP sponsor with respect to a prescription drug
4 plan.

5 “(3) FALLBACK SERVICE AREA.—For purposes
6 of this subsection, the term ‘comprehensive fallback
7 service area’ means, for a PDP region with respect
8 to a year, any area within such region for which the
9 Secretary determines before the beginning of the
10 year that the access requirements of the first sen-
11 tence of section 1860D–3(a)(1)(B) will not be met
12 for part D eligible individuals residing in the area
13 for the year.

14 “(4) COMPREHENSIVE FALLBACK PRESCRIP-
15 TION DRUG PLAN.—For purposes of this part, the
16 term ‘comprehensive fallback prescription drug plan’
17 means a prescription drug plan that—

18 “(A) offers the standard prescription drug
19 coverage and access to negotiated prices de-
20 scribed in section 1860D–2(a)(1)(A);

21 “(B) offers coverage of covered part D
22 drugs after an individual has reached the initial
23 coverage limit under paragraph (3) of section
24 1860D–2(b) but has not reached the annual
25 out-of-pocket threshold under paragraph (4)(B)

1 of such section that is the same as the coverage
2 for such drugs that is offered after the indi-
3 vidual has met the deductible under paragraph
4 (1) of such section but has not reached such
5 initial coverage limit; and

6 “(C) meets such other requirements as the
7 Secretary may specify.

8 “(5) MONTHLY BENEFICIARY PREMIUM.—Ex-
9 cept as provided in section 1860D–13(b) (relating to
10 late enrollment penalty) and subject to section
11 1860D–14 (relating to low-income assistance), the
12 monthly beneficiary premium to be charged under a
13 comprehensive fallback prescription drug plan of-
14 fered in all comprehensive fallback service areas in
15 a PDP region shall be uniform and shall be an
16 amount equal to—

17 “(A) 25.5 percent of an amount equal to
18 the Secretary’s estimate of the average monthly
19 per capita actuarial cost, including administra-
20 tive expenses, under the comprehensive fallback
21 prescription drug plan of providing the coverage
22 described in paragraph (4)(A) in the region, as
23 calculated by the Chief Actuary of the Centers
24 for Medicare & Medicaid Services; and

1 “(B) 100 percent of an amount equal to
2 the Secretary’s estimate of the average monthly
3 per capita actuarial cost, including administra-
4 tive expenses, under the comprehensive fallback
5 prescription drug plan of providing the coverage
6 described in paragraph (4)(B) in the region, as
7 calculated by the Chief Actuary of the Centers
8 for Medicare & Medicaid Services.

9 In calculating such administrative expenses, the
10 Chief Actuary shall use a factor that is based on
11 similar expenses of prescription drug plans that are
12 not standard or comprehensive fallback prescription
13 drug plans.

14 “(6) INCORPORATION OF STANDARD FALLBACK
15 PRESCRIPTION DRUG PLAN PROVISIONS.—The provi-
16 sions of paragraphs (1)(B), (5), and (7) of sub-
17 section (g) shall apply to comprehensive fallback pre-
18 scription drug plans and entities offering such plans
19 in the same manner as such provisions apply to
20 standard fallback prescription drug plans and enti-
21 ties offering such plans.

22 “(7) SAME ENTITY MAY OFFER BOTH FALL-
23 BACK PRESCRIPTION DRUG PLANS IN AN AREA.—
24 The Secretary may award a contract to an entity
25 under this subsection with respect to an area and

1 period and a contract under subsection (g) with re-
2 spect to the same area and period.”.

3 (c) CONFORMING AMENDMENTS.—

4 (1) ACCESS.—Section 1860D–3 of the Social
5 Security Act (42 U.S.C. 1395w–103) is amended—

6 (A) in subsection (a)—

7 (i) in paragraph (1)(A) of subsection
8 (a), as redesignated by subsection (a), by
9 inserting “standard” before “fallback”;
10 and

11 (ii) in paragraph (2), by striking
12 “paragraph (1)” and inserting “paragraph
13 (1)(A)”; and

14 (B) in subsection (b)(2), by striking “fall-
15 back prescription drug plan for that area under
16 section 1860D–11(g)” and inserting “standard
17 or comprehensive fallback prescription drug
18 plan for that area under subsections (g) and (k)
19 of section 1860D–11, as applicable”.

20 (2) LIMITED RISK PLANS.—Section 1860D–
21 11(f) of the Social Security Act (42 U.S.C. 1395w–
22 111(f)) is amended—

23 (A) in paragraph (1)—

24 (i) by striking “1860D–3(a)” and in-
25 serting “1860D–3(a)(1)(A)”; and

1 (ii) by inserting “standard” before
2 “fallback”; and

3 (B) in paragraph (2)(A), by striking
4 “1860D–3(a)” and inserting “1860D–
5 3(a)(1)(A)”; and

6 (C) in each of subparagraphs (A) and (B)
7 of paragraph (4), by striking “a fallback” and
8 inserting “a standard or comprehensive fall-
9 back”.

10 (3) STANDARD FALLBACK PRESCRIPTION DRUG
11 PLAN.—Section 1860D–11(g) of the Social Security
12 Act (42 U.S.C. 1395w–111(g)) is amended—

13 (A) in the heading, by inserting “STAND-
14 ARD PRESCRIPTION DRUG” after “ACCESS TO”;

15 (B) by inserting “STANDARD” before
16 “FALLBACK” each place it appears;

17 (C) by striking “FALLBACK” each place it
18 appears and inserting “STANDARD FALLBACK”;

19 (D) by inserting “standard” before “fall-
20 back” each place it appears; and

21 (E) in paragraph (3), by striking “1860D–
22 3(a)” and inserting “1860D–3(a)(1)(A)”.

23 (4) ANNUAL REPORT.—Section 1860D–11(h) of
24 the Social Security Act (42 U.S.C. 1395w–111(h)) is

1 amended by striking “(f) and (g)” and inserting
2 “(f), (g), and (k)”.

3 (5) LIMITATION ON ENTITIES OFFERING FALL-
4 BACK PRESCRIPTION DRUG PLANS.—Section 1860D-
5 12(b)(2) of the Social Security Act (42 U.S.C.
6 1395w-112(b)(2)) is amended—

7 (A) in the matter preceding subparagraph
8 (A), by striking “a fallback” and inserting “a
9 standard or comprehensive fallback”;

10 (B) in subparagraph (A)—

11 (i) by striking “section 1860D-11(g)”
12 and inserting “subsection (g) or (k) of sec-
13 tion 1860D-11”;

14 (ii) by striking “such section” and in-
15 serting “such subsections, as applicable”;
16 and

17 (iii) by striking “a fallback” and in-
18 serting “a standard or comprehensive fall-
19 back”;

20 (C) in subparagraph (B), by striking “a
21 fallback” and inserting “a standard or com-
22 prehensive fallback”;

23 (D) in subparagraph (C), by striking “a
24 fallback” and inserting “a standard or com-
25 prehensive fallback” and

1 (E) in the flush matter following subpara-
2 graph (C), by striking “a fallback” and insert-
3 ing “a standard or comprehensive fallback”.

4 (6) COLLECTION OF PREMIUM.—Section
5 1860D–13(c)(3) of the Social Security Act (42
6 U.S.C. 1395w–113(c)(3)) is amended by striking “a
7 fallback” and inserting “a standard or comprehen-
8 sive fallback”.

9 (7) PAYMENT.—Section 1860D–15(g) of the
10 Social Security Act (42 U.S.C. 1395w–115(g)) is
11 amended by striking “offering” and all that follows
12 and inserting the following: “offering—

13 “(1) a standard prescription drug plan (as de-
14 fined in paragraph (4) of section 1860D–11(g)), the
15 amount payable shall be the amounts determined
16 under the contract for such plan pursuant to para-
17 graph (5) of such section; and

18 “(2) a comprehensive prescription drug plan (as
19 defined in paragraph (4) of section 1860D–11(k)),
20 the amount payable shall be the amounts determined
21 under the contract for such plan pursuant to such
22 paragraph (5) (as made applicable to section
23 1860D–11(k) under paragraph (6) of such sec-
24 tion).”.

1 (8) PAYMENT FROM ACCOUNT.—Section
2 1860D–16(b)(1)(B) of the Social Security Act (42
3 U.S.C. 1395w–116(b)(1)(B)) is amended by insert-
4 ing “standard and comprehensive” before “fall-
5 back”.

6 (9) DEFINITION.—Section 1860D–41(a)(5) of
7 the Social Security Act (42 U.S.C. 1395w–
8 151(a)(5)) is amended to read as follows:

9 “(5) STANDARD FALLBACK PRESCRIPTION
10 DRUG PLAN; COMPREHENSIVE FALLBACK PRESCRIP-
11 TION DRUG PLAN.—The terms ‘standard fallback
12 prescription drug plan’ and ‘comprehensive fallback
13 prescription drug plan’ have the meaning given those
14 terms in subsection (g)(4) and (k)(4), respectively,
15 of section 1860D–11.”.

16 (d) EFFECTIVE DATE.—The amendments made by
17 this section shall take effect on January 1, 2012.

○