

112TH CONGRESS
1ST SESSION

S. _____

To reduce the costs of prescription drugs under the Medicare program,
and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. KOHL introduced the following bill; which was read twice and referred to
the Committee on _____

A BILL

To reduce the costs of prescription drugs under 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; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Prescription Drug Cost Reduction Act”.

6 (b) **TABLE OF CONTENTS.**—The table of contents for
7 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Medicare part B drug rebate program.
- Sec. 3. Negotiation of drug prices under Medicare Part B.
- Sec. 4. Payment for least costly alternative for Medicare part B drugs.
- Sec. 5. Study and report on physician reimbursement for drugs and biologicals
under Medicare part B.
- Sec. 6. Requirements of pharmacy benefit managers.

Sec. 7. Certification for off-label prescribing of certain drugs prescribed in a nursing home setting.

Sec. 8. Expansion of 340B program covered entities to include PACE programs.

1 **SEC. 2. MEDICARE PART B DRUG REBATE PROGRAM.**

2 Section 1842 of the Social Security Act (42 U.S.C.
3 1395u) is amended by adding at the end the following new
4 subsection:

5 “(v)(1) Not later than 2 years after the date of enact-
6 ment of this subsection, the Secretary shall establish a
7 program under which a manufacturer shall provide a re-
8 bate to the Secretary for drugs or biologicals of the manu-
9 facturer that are furnished under this part.

10 “(2) The program established under paragraph (1)—

11 “(A) shall be similar to rebate agreements
12 under section 1927 (including the application of an
13 additional rebate for certain drugs whose costs ex-
14 ceed an annual inflation target as described in sub-
15 section (c)(2) of such section); and

16 “(B) may use the average manufacturer price
17 (as determined under section 1927(k)(1)) or the av-
18 erage sales price (as defined in section 1847A(c)) as
19 the basis for calculating the amount of the rebate
20 under the program.

21 “(3) The Secretary shall promulgate regulations to
22 carry out this subsection.”.

1 **SEC. 3. NEGOTIATION OF DRUG PRICES UNDER MEDICARE**

2 **PART B.**

3 (a) IN GENERAL.—Section 1842 of the Social Secu-
4 rity Act (42 U.S.C. 1395u), as amended by section 2, is
5 amended by adding at the end the following new sub-
6 section:

7 “(w) NEGOTIATION OF PRICES FOR DRUGS AND
8 BIOLOGICALS.—

9 “(1) IN GENERAL.—Notwithstanding any other
10 provision of law, the Secretary shall negotiate a con-
11 tract with a manufacturer to establish the amount of
12 payment under this part for any drug or biological
13 for which the program under this part is the major-
14 ity purchaser (as determined under paragraph (2)).
15 The Secretary shall negotiate such contracts with
16 the goal of ensuring appropriate and adequate ac-
17 cess to necessary drugs and biologicals for individ-
18 uals enrolled under this part, while minimizing costs
19 to such individuals and to the program under this
20 part to the greatest extent possible.

21 “(2) MAJORITY PURCHASER.—For purposes of
22 paragraph (1), the Secretary shall, by regulation, es-
23 tablish a method to identify, based upon drug utili-
24 zation rates, any drug or biological for which greater
25 than 50 percent of the units sold by the manufac-
26 turer of such drug or biological in the preceding cal-

1 endar year were provided to individuals enrolled
2 under this part.

3 “(3) DEFINITIONS.—In this subsection:

4 “(A) DRUGS AND BIOLOGICALS.—The
5 term ‘drug’ and the term ‘biological’ have the
6 same meaning as provided under section
7 1861(t).

8 “(B) MANUFACTURER.—The term ‘manu-
9 facturer’ has the same meaning as provided
10 under section 1847A(c)(6)(A).”.

11 (b) EFFECTIVE DATE.—The amendments made by
12 this section shall apply to drugs and biologicals that are
13 furnished on or after July 1, 2012.

14 **SEC. 4. PAYMENT FOR LEAST COSTLY ALTERNATIVE FOR**
15 **MEDICARE PART B DRUGS.**

16 Section 1847A(b) of the Social Security Act (42
17 U.S.C. 1395w-3a(b)) is amended—

18 (1) in paragraph (1), in the matter preceding
19 subparagraph (A), by striking “paragraph (7)” and
20 inserting “paragraphs (7) and (9)”; and

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

23 “(9) TREATMENT OF FUNCTIONALLY EQUIVA-
24 LENT DRUGS AND BIOLOGICALS.—In the case of a
25 drug or biological furnished on or after the date that

1 is 180 days after the date of enactment of this para-
2 graph, for which payment is determined under this
3 section, if the drug or biological is functionally
4 equivalent (as defined by the Secretary) to another
5 drug or biological for which payment is determined
6 under this section, the amount of payment for both
7 such drugs or biologicals shall be equal to the pay-
8 ment amount otherwise determined under this sec-
9 tion (without regard to the application of this para-
10 graph) for the least costly of such drugs or
11 biologicals.”.

12 **SEC. 5. STUDY AND REPORT ON PHYSICIAN REIMBURSE-**
13 **MENT FOR DRUGS AND BIOLOGICALS UNDER**
14 **MEDICARE PART B.**

15 (a) STUDY.—The Secretary of Health and Human
16 Services (in this section referred to as the “Secretary”)
17 shall conduct a study on physician reimbursement for
18 drugs and biologicals furnished under part B of title
19 XVIII of the Social Security Act (42 U.S.C. 1395j et
20 seq.). Such study shall include an evaluation and assess-
21 ment of the following:

22 (1) The ability of physicians to afford and prof-
23 it from drugs and biologicals purchased at the cur-
24 rent reimbursement rate of average sales price plus
25 6 percent under section 1847A of the Social Security

1 Act (42 U.S.C. 1395w-3a), including any profit
2 margins with respect to such drugs and biologicals.

3 (2) The rate at which physicians furnish the
4 higher priced drug or biological under such part
5 when there is a cheaper alternative drug or biological.
6 cal.

7 (3) The feasibility and merits of other reim-
8 bursement structures that are not based on the price
9 of the drug or biological, such as a flat, universal fee
10 issued for every drug or biological furnished under
11 such part, or any other relevant reimbursement
12 structures.

13 (b) CONSULTATION.—In conducting the study under
14 subsection (a), the Secretary shall consult with the Admin-
15 istrator of the Centers for Medicare & Medicaid Services
16 and the Inspector General of the Department of Health
17 and Human Services.

18 (c) REPORT.—

19 (1) IN GENERAL.—Not later than 1 year after
20 the date of enactment of this Act, the Secretary
21 shall submit to Congress a report containing the re-
22 sults of the study conducted under subsection (a),
23 together with recommendations for changing physi-
24 cian reimbursement for drugs and biologicals under
25 Medicare part B.

1 (2) CONSIDERATION OF RECOMMENDATIONS TO
2 REMOVE INCENTIVES TO PRESCRIBE HIGHER PRICED
3 DRUGS.—In making recommendations under para-
4 graph (1), the Secretary shall consider including rec-
5 ommendations that would—

6 (A) move reimbursement for drugs and
7 biologicals under Medicare part B away from
8 being based on the price of the drug or biologi-
9 cal; and

10 (B) reduce or eliminate incentives to fur-
11 nish higher priced drugs and biologicals under
12 such part.

13 **SEC. 6. REQUIREMENTS OF PHARMACY BENEFIT MAN-**
14 **AGERS.**

15 (a) IN GENERAL.—A pharmacy benefit manager (re-
16 ferred to in this section as a “PBM”) shall owe a fiduciary
17 duty, in accordance with this section, to each covered enti-
18 ty.

19 (b) COVERED ENTITY DEFINED.—In this section, the
20 term “covered entity” means the head of each Federal
21 agency with which the PBM contracts, including—

22 (1) the Secretary of Health and Human Serv-
23 ices with respect to the programs under part C of
24 title XVIII of the Social Security Act (42 U.S.C.
25 1395w–21 et seq.) and Part D of such title;

1 drug that is more expensive than a drug pre-
2 scribed;

3 (C) in the case that a PBM receives a pay-
4 ment or benefit for increasing volume of sales
5 for a particular drug, class of drug, or brand of
6 drug, disclose the payment or benefit with the
7 covered entity; and

8 (D) disclose to covered entities all financial
9 terms and arrangements between the PBM and
10 a pharmaceutical drug company, including for-
11 mulary management and drug-switch agree-
12 ments, educational support, claims processing
13 and pharmacy network fees that are charged
14 from retail pharmacies, data sales fees, and
15 other direct or indirect remunerations, includ-
16 ing discounts, charge backs or rebates, cash dis-
17 counts, free goods contingent on a purchase
18 agreement, up-front payments, coupons, goods
19 in-kind, free or reduced-price services, grants,
20 or other price concessions or similar benefits of-
21 fered to some or all purchasers from any
22 source, including manufacturers, pharmacies,
23 enrollees, or any other person that would serve
24 to decrease the costs incurred under the plan.

1 (2) REPORTING OF DRUG SUBSTITUTIONS.—

2 The Secretary of Health and Human Services shall
3 establish categories that describe reasons, such as a
4 concern about drug interactions or discretion of the
5 PBM, for a PBM to substitute a drug that costs
6 more than the drug prescribed to an individual by
7 a practitioner, as described in paragraph (1)(A). In
8 reporting drug substitutions under such paragraph,
9 a PBM shall state the category under which each
10 type of substitution falls.

11 (3) DIRECT OR INDIRECT REMUNERATION.—

12 For purposes of paragraph (1)(D), the term “direct
13 or indirect remuneration” includes discounts,
14 chargebacks or rebates, cash discounts, free goods
15 contingent on a purchase agreement, up-front pay-
16 ments, coupons, goods in-kind, free or reduced-price
17 services, grants, or other price concessions or similar
18 benefits from manufacturers, pharmacies or similar
19 entities obtained by an intermediary contracting or-
20 ganization with which the plan sponsor has con-
21 tracted, regardless of whether the intermediary con-
22 tracting organization retains all or a portion of the
23 direct and indirect remuneration or passes the entire
24 direct and indirect remuneration to the plan sponsor
25 and regardless of the terms of the contract between

1 the plan sponsor and the intermediary contracting
2 organization.

3 (d) CONFIDENTIALITY.—

4 (1) IN GENERAL.—A PBM may require covered
5 entities to keep the information described in sub-
6 section (c)(4) confidential.

7 (2) RESTRICTIONS ON THE USE OF INFORMA-
8 TION.—

9 (A) IN GENERAL.—Officers, employees,
10 and contractors of the Department of Health
11 and Human Services may use the information
12 disclosed or obtained in accordance with the
13 provisions of this Act only for the purposes of,
14 and to the extent necessary in, carrying out this
15 Act, including determination of payments, pay-
16 ment-related oversight, and program integrity
17 activities.

18 (B) LIMITATIONS.—

19 (i) AUTHORITY OF THE OIG.—The re-
20 striction described in subparagraph (A)
21 does not limit the authority of the Inspec-
22 tor General of the United States to fulfill
23 the responsibilities of the Inspector Gen-
24 eral in accordance with applicable Federal
25 law.

1 (ii) AUTHORITY OF CMS.—The restric-
2 tion described in subparagraph (A) does
3 not limit the authority of the Centers for
4 Medicare & Medicaid Services to use data
5 regarding drug claims in accordance with
6 section 1848(m) of the Social Security Act
7 (42 U.S.C. 1395w-4(m)).

8 (e) AUDITS.—To ensure compliance with the require-
9 ments of this section, each covered entity shall conduct
10 audits of the PBMs with which the covered entity con-
11 tracts.

12 **SEC. 7. CERTIFICATION FOR OFF-LABEL PRESCRIBING OF**
13 **CERTAIN DRUGS PRESCRIBED IN A NURSING**
14 **HOME SETTING.**

15 Title XVIII of the Social Security Act (42 U.S.C.
16 1395 et seq.) is amended by adding at the end the fol-
17 lowing new section:

18 “CERTIFICATION FOR OFF-LABEL PRESCRIBING OF CER-
19 TAIN DRUGS PRESCRIBED IN A NURSING HOME SET-
20 TING

21 “SEC. 1899B. (a) IN GENERAL.—The Secretary shall
22 develop a form for use by physicians and practitioners (as
23 defined in section 1842(b)(18)(C)) to certify that, in the
24 case of an applicable drug prescribed for an off-label use
25 under this title, such use is for a medically accepted indi-
26 cation.

1 “(b) DEFINITIONS.—In this section:

2 “(1) APPLICABLE DRUG.—The term ‘applicable
3 drug’ means an atypical antipsychotic prescribed for
4 use in a nursing home setting (as defined by the
5 Secretary).

6 “(2) OFF-LABEL USE.—The term ‘off-label use’
7 means a use which has not been approved by the
8 Food and Drug Administration.

9 “(3) MEDICALLY ACCEPTED INDICATION.—The
10 term ‘medically accepted indication’ means the appli-
11 cable drug is included in the compendia described in
12 section 1861(t)(1) or is approved by a committee de-
13 scribed in such section (or, in the case of an applica-
14 ble drug that is a covered part D drug (as defined
15 in section 1860D–2(e)), has the meaning given such
16 term in paragraph (4) of such section 1860D–2(e)).

17 “(c) REGULATIONS.—The Secretary shall establish
18 by regulation requirements that, effective not later than
19 1 year after the date of enactment of this section, physi-
20 cians and practitioners use the form developed under sub-
21 section (a) to make the certification under such subsection
22 with respect to an applicable drug prescribed by the physi-
23 cian or practitioner for an off-label use under this title.
24 In order to carry out these requirements in a timely man-
25 ner, the Secretary shall promulgate regulations that take

1 effect on an interim basis, after notice and pending oppor-
2 tunity for public comment.”.

3 **SEC. 8. EXPANSION OF 340B PROGRAM COVERED ENTITIES**
4 **TO INCLUDE PACE PROGRAMS.**

5 (a) EXPANSION.—Section 340B(a) of the Public
6 Health Service Act (42 U.S.C. 256b(a)) is amended

7 (1) in paragraph (4), by adding at the end the
8 following:

9 “(P) An entity that is a PACE provider of-
10 fering a PACE program under section 1894
11 and section 1934 of the Social Security Act.”;
12 and

13 (2) in paragraph (5)(A), by adding at the end
14 the following:

15 “(iii) ADDITIONAL MECHANISM.—The
16 Secretary shall establish a mechanism to
17 ensure that a manufacturer does not pay a
18 duplicate discount with respect to a drug
19 that is subject to an agreement under this
20 section if the PACE program receives any
21 rebate (including any negotiated price con-
22 cessions) for the drug under part D of title
23 XVIII of the Social Security Act. Such
24 mechanism shall be similar to the mecha-
25 nism established under clause (ii).”.

1 (b) REQUIREMENTS.—

2 (1) MEDICARE.—Section 1894(e) of the Social
3 Security Act (42 U.S.C. 1395eee(e)) is amended by
4 adding at the end the following new paragraph:

5 “(9) PARTICIPATION IN 340B PROGRAM.—

6 “(A) IN GENERAL.—In the case of a
7 PACE program that serves part D eligible indi-
8 viduals who are enrolled under such program,
9 the PACE program agreement for such pro-
10 gram shall require the PACE provider offering
11 the program to participate in the drug discount
12 program under section 340B of the Public
13 Health Service Act for purposes of purchasing
14 covered part D drugs with respect to qualified
15 prescription drug coverage provided to such in-
16 dividuals.

17 “(B) ATTESTATION.—The Secretary may
18 accept an attestation by a PACE provider, at
19 the time of submitting a bid pursuant to section
20 1860D–21(f), as sufficient evidence of partici-
21 pation in the drug discount program under sec-
22 tion 340B of the Public Health Service Act for
23 purposes of subparagraph (A).

24 “(C) ENSURING TIMELY ACCESS TO COV-
25 ERED OUTPATIENT DRUGS.—Nothing in this

1 paragraph shall prevent a PACE program from
2 providing enrollees access to covered outpatient
3 drugs (including covered part D drugs) through
4 a retail community pharmacy (as defined in sec-
5 tion 1927(k)(10)) that is not a contract phar-
6 macy under the drug discount program under
7 section 340B of the Public Health Service Act
8 in the case where such access is necessary to
9 ensure that such drugs are dispensed to enroll-
10 ees on a timely basis.

11 “(D) DEFINITIONS.—In this paragraph:

12 “(i) COVERED OUTPATIENT DRUG.—
13 The term ‘covered outpatient drug’ has the
14 meaning given such term for purposes of
15 section 340B of the Public Health Service
16 Act.

17 “(ii) COVERED PART D DRUG.—The
18 term ‘covered part D drug’ has the mean-
19 ing given such term in section 1860D–2(e).

20 “(iii) PART D ELIGIBLE INDI-
21 VIDUAL.—The term ‘part D eligible indi-
22 vidual’ has the meaning given such term in
23 section 1860D–1(a)(3)(A).

24 “(iv) QUALIFIED PRESCRIPTION DRUG
25 COVERAGE.—The term ‘qualified prescrip-

1 tion drug coverage’ has the meaning given
2 such term in section 1860D–2(a).”.

3 (2) MEDICAID.—Section 1934(e) of the Social
4 Security Act (42 U.S.C. 1396u–4(e)) is amended by
5 adding at the end the following new paragraph:

6 “(9) PARTICIPATION IN 340B PROGRAM.—

7 “(A) IN GENERAL.—In the case of a
8 PACE program that serves part D eligible indi-
9 viduals who are enrolled under such program,
10 the PACE program agreement for such pro-
11 gram shall require the PACE provider offering
12 the program to participate in the drug discount
13 program under section 340B of the Public
14 Health Service Act for purposes of purchasing
15 covered part D drugs with respect to qualified
16 prescription drug coverage provided to such in-
17 dividuals.

18 “(B) ATTESTATION.—The Secretary may
19 accept an attestation by a PACE provider, at
20 the time of submitting a bid pursuant to section
21 1860D–21(f), as sufficient evidence of partici-
22 pation in the drug discount program under sec-
23 tion 340B of the Public Health Service Act for
24 purposes of subparagraph (A).

1 “(C) ENSURING TIMELY ACCESS TO COV-
2 ERED OUTPATIENT DRUGS.—Nothing in this
3 paragraph shall prevent a PACE program from
4 providing enrollees access to covered outpatient
5 drugs (including covered part D drugs) through
6 a retail community pharmacy (as defined in sec-
7 tion 1927(k)(10)) that is not a contract phar-
8 macy under the drug discount program under
9 section 340B of the Public Health Service Act
10 in the case where such access is necessary to
11 ensure that such drugs are dispensed to enroll-
12 ees on a timely basis.

13 “(D) DEFINITIONS.—In this paragraph:

14 “(i) COVERED OUTPATIENT DRUG.—
15 The term ‘covered outpatient drug’ has the
16 meaning given such term for purposes of
17 section 340B of the Public Health Service
18 Act.

19 “(ii) COVERED PART D DRUG.—The
20 term ‘covered part D drug’ has the mean-
21 ing given such term in section 1860D–2(e).

22 “(iii) PART D ELIGIBLE INDI-
23 VIDUAL.—The term ‘part D eligible indi-
24 vidual’ has the meaning given such term in
25 section 1860D–1(a)(3)(A).

1 “(iv) QUALIFIED PRESCRIPTION DRUG
2 COVERAGE.—The term ‘qualified prescrip-
3 tion drug coverage’ has the meaning given
4 such term in section 1860D–2(a).”.

5 (3) EFFECTIVE DATE.—The amendments made
6 by this subsection shall apply to PACE program
7 agreements entered into on or after the date that is
8 2 years after the date of enactment of this section.

9 (c) INCLUSION OF SAVINGS IN BIDS SUBMITTED BY
10 PACE PROGRAMS PROVIDING QUALIFIED PRESCRIPTION
11 DRUG COVERAGE.—

12 (1) IN GENERAL.—Section 1860D–21(f) of the
13 Social Security Act (42 U.S.C. 1395w–131(f)) is
14 amended by adding at the end the following new
15 paragraph:

16 “(4) PARTICIPATION IN 340B PROGRAM.—

17 “(A) INCLUSION OF SAVINGS IN BIDS SUB-
18 MITTED.—

19 “(i) DETERMINATION OF SAVINGS.—
20 An organization offering prescription drug
21 coverage under this subsection shall deter-
22 mine the estimated annual savings to the
23 organization as a result of participation in
24 the drug discount program under section
25 340B of the Public Health Service Act (as

1 described in sections 1894(e)(2)(C) and
2 1934(e)(2)(C)).

3 “(ii) INCLUSION IN BIDS SUB-
4 MITTED.—The bid of an organization of-
5 fering prescription drug coverage under
6 this subsection shall reflect the estimated
7 savings determined by the organization
8 under clause (i) for the plan year involved,
9 and shall take into account any additional
10 costs to the organization as a result of the
11 implementation and administration of such
12 drug discount program during the plan
13 year involved. Such bid shall include an at-
14 testation by the organization that such
15 savings are reflected in the bid amount.

16 “(iii) CONSIDERATION OF APPLICABLE
17 CEILING PRICES.—In making the deter-
18 mination under clause (i), the organization
19 shall consider the applicable ceiling prices
20 for covered outpatient drugs (using the ac-
21 cess provided under section
22 340B(d)(1)(B)(iii) of the Public Health
23 Service Act).

24 “(B) RECEIPT OF PERCENTAGE OF SAV-
25 INGS.—

1 “(i) IN GENERAL.—Subject to clause
2 (ii), an organization offering prescription
3 drug coverage under this subsection shall
4 be eligible to receive from the Secretary an
5 amount equal to 10 percent of the esti-
6 mated annual savings to the Federal gov-
7 ernment (as determined by the Secretary
8 under regulations promulgated under sub-
9 paragraph (C)) to the organization as a re-
10 sult of participation in the drug discount
11 program under section 340B of the Public
12 Health Service Act (as described in sec-
13 tions 1894(e)(2)(C) and 1934(e)(2)(C)). In
14 making the determination under the pre-
15 ceding sentence, the Secretary shall con-
16 sider the determination of the organization
17 under subparagraph (A)(i).

18 “(ii) REQUIREMENTS.—An organiza-
19 tion shall only be eligible to receive the
20 amount under clause (i) for the plan year
21 involved if the organization—

22 “(I) submits to the Secretary an
23 application in such form and manner,
24 and containing such information, as
25 the Secretary may specify; and

1 “(II) has in effect a plan ap-
2 proved by the Secretary for the use of
3 any amounts received under such
4 clause to—

5 “(aa) provide to enrollees
6 enhanced formulary coverage,
7 medication management, or dis-
8 ease management;

9 “(bb) invest in the develop-
10 ment of the organization (includ-
11 ing through the use of a signifi-
12 cant proportion of the savings to
13 invest in the development and
14 use of qualified electronic health
15 records (as defined in section
16 3000(13) of the Public Health
17 Service Act) or other health in-
18 formation technology); or

19 “(cc) carry out other initia-
20 tives approved by the Secretary.

21 “(C) REGULATIONS.—The Secretary shall
22 promulgate regulations to carry out this para-
23 graph and sections 1894(e)(9) and
24 1934(e)(9).”.

1 (2) EFFECTIVE DATE.—The amendment made
2 by this subsection shall apply to plan years begin-
3 ning on or after the date that is 2 years after the
4 date of enactment of this Act.

5 (d) NOT TREATED AS CHANGE IN LAW FOR PUR-
6 POSES OF DETERMINING MANUFACTURER COMPLI-
7 ANCE.—Section 1927(a)(5) of the Social Security Act (42
8 U.S.C. 1396r–8(a)(5)) is amended—

9 (1) in subparagraph (D)—

10 (A) by striking “AMENDMENTS.—In deter-
11 mining” and inserting “AMENDMENTS.—

12 “(i) IN GENERAL.—Subject to clause
13 (ii), in determining”; and

14 (B) by adding at the end the following new
15 clause:

16 “(ii) EXCEPTION.—The Secretary
17 shall take into account the amendments
18 made by section 9 of the Prescription Drug
19 Cost Reduction Act for purposes of deter-
20 mining whether an agreement under sub-
21 paragraph (A) meets the requirements of
22 section 340B of the Public Health Service
23 Act and an agreement under such subpara-
24 graph shall not be determined to meet such
25 requirements if it does not meet the re-

1 requirements under such section with respect
2 to covered outpatient drugs purchased by a
3 covered entity described in subsection
4 (a)(4)(P) of such section on or after the
5 date that is 1 year after the date of enact-
6 ment of such Act.”; and

7 (2) in subparagraph (E)—

8 (A) by striking “COMPLIANCE.—A manu-
9 facturer” and inserting “COMPLIANCE.—

10 “(i) IN GENERAL.—Subject to clause

11 (ii), a manufacturer”; and

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

14 “(ii) EXCEPTION.—The amendments
15 made by section 9 of the Prescription Drug
16 Cost Reduction Act shall not be treated as
17 a legislative change for purposes of apply-
18 ing clause (i) and a manufacturer shall not
19 be deemed to be in compliance with the re-
20 quirements of this paragraph if the manu-
21 facturer has not entered into an agreement
22 with the Secretary that meets the require-
23 ments under section 340B of the Public
24 Health Service Act with respect to covered
25 outpatient drugs purchased by a covered

1 entity described in subsection (a)(4)(P) of
2 such section on or after the date that is 1
3 year after the date of enactment of such
4 Act.”.