112TH CONGRESS
1ST SESSION

S. 1699

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

IN THE SENATE OF THE UNITED STATES

OCTOBER 12, 2011

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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Prescription Drug Cost Reduction Act''.

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

SEC. 2. MEDICARE PART B DRUG REBATE PROGRAM.

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

''(v)(1) Not later than 2 years after the date of enactment of this subsection, the Secretary shall establish a program under which a manufacturer shall provide a rebate to the Secretary for drugs or biologicals of the manufacturer that are furnished under this part.

''(2) The program established under paragraph (1)—

''(A) shall be similar to rebate agreements under section 1927 (including the application of an additional rebate for certain drugs whose costs exceed an annual inflation target as described in subsection (c)(2) of such section); and

''(B) may use the average manufacturer price (as determined under section 1927(k)(1)) or the average sales price (as defined in section 1847A(c)) as the basis for calculating the amount of the rebate under the program.

''(3) The Secretary shall promulgate regulations to carry out this subsection.''.

SEC. 3. NEGOTIATION OF DRUG PRICES UNDER MEDICARE PART B.

(a) IN GENERAL.—Section 1842 of the Social Security Act (42 U.S.C. 1395u), as amended by section 2, is amended by adding at the end the following new subsection:

''(w) NEGOTIATION OF PRICES FOR DRUGS AND BIOLOGICALS.—

''(1) IN GENERAL.—Notwithstanding any other provision of law, the Secretary shall negotiate a contract with a manufacturer to establish the amount of payment under this part for any drug or biological for which the program under this part is the majority purchaser (as determined under paragraph (2)). The Secretary shall negotiate such contracts with the goal of ensuring appropriate and adequate access to necessary drugs and biologicals for individuals enrolled under this part, while minimizing costs to such individuals and to the program under this part to the greatest extent possible.

''(2) MAJORITY PURCHASER.—For purposes of paragraph (1), the Secretary shall, by regulation, establish a method to identify, based upon drug utilization rates, any drug or biological for which greater than 50 percent of the units sold by the manufacturer of such drug or biological in the preceding cal-

endar year were provided to individuals enrolled under this part.

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

''(A) DRUGS AND BIOLOGICALS.—The term 'drug' and the term 'biological' have the same meaning as provided under section 1861(t).

''(B) MANUFACTURER.—The term 'manufacturer' has the same meaning as provided under section 1847A(c)(6)(A).''.

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

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

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

(1) in paragraph (1), in the matter preceding subparagraph (A), by striking ''paragraph (7)'' and inserting ''paragraphs (7) and (9)''; and

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

''(9) TREATMENT OF FUNCTIONALLY EQUIVALENT DRUGS AND BIOLOGICALS.—In the case of a drug or biological furnished on or after the date that

is 180 days after the date of enactment of this paragraph, for which payment is determined under this section, if the drug or biological is functionally equivalent (as defined by the Secretary) to another drug or biological for which payment is determined under this section, the amount of payment for both such drugs or biologicals shall be equal to the payment amount otherwise determined under this section (without regard to the application of this paragraph) for the least costly of such drugs or biologicals.''.

SEC. 5. STUDY AND REPORT ON PHYSICIAN REIMBURSEMENT FOR DRUGS AND BIOLOGICALS UNDER MEDICARE PART B.

(a) STUDY.—The Secretary of Health and Human Services (in this section referred to as the ''Secretary'') shall conduct a study on physician reimbursement for drugs and biologicals furnished under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.). Such study shall include an evaluation and assessment of the following:

(1) The ability of physicians to afford and profit from drugs and biologicals purchased at the current reimbursement rate of average sales price plus 6 percent under section 1847A of the Social Security

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

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

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

(b) CONSULTATION.—In conducting the study under subsection (a), the Secretary shall consult with the Administrator of the Centers for Medicare & Medicaid Services and the Inspector General of the Department of Health and Human Services.

(c) REPORT.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary shall submit to Congress a report containing the results of the study conducted under subsection (a), together with recommendations for changing physician reimbursement for drugs and biologicals under Medicare part B.

(2) CONSIDERATION OF RECOMMENDATIONS TO REMOVE INCENTIVES TO PRESCRIBE HIGHER PRICED DRUGS.—In making recommendations under paragraph (1), the Secretary shall consider including recommendations that would—

(A) move reimbursement for drugs and biologicals under Medicare part B away from being based on the price of the drug or biological; and

(B) reduce or eliminate incentives to furnish higher priced drugs and biologicals under such part.

SEC. 6. REQUIREMENTS OF PHARMACY BENEFIT MANAGERS.

(a) IN GENERAL.—A pharmacy benefit manager (referred to in this section as a ''PBM'') shall owe a fiduciary duty, in accordance with this section, to each covered entity.

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

(1) the Secretary of Health and Human Services with respect to the programs under part C of title XVIII of the Social Security Act (42 U.S.C. 1395w–21 et seq.) and part D of such title;

(2) the Secretary of Veterans Affairs with respect to health coverage offered through the Department of Veterans Affairs;

(3) the Secretary of Defense with respect to the TRICARE program under chapter 55 of title 10, United States Code; and

(4) the Director of the Office of Personnel Management with respect to the Federal employee health benefits program under chapter 89 of title 5, United States Code.

(c) REQUIREMENTS.—

(1) IN GENERAL.—The fiduciary duty described in subsection (a) shall include the duty to—

(A) notify each covered entity, on a quarterly basis, if the PBM substitutes a drug that costs more than the drug prescribed to an individual by a practitioner, and disclose the aggregate costs of the drug prescribed and the drug provided by the PBM and any benefit or payment directly or indirectly received by the PBM as a result of the substitution for all individuals receiving such substitute drug during the applicable quarter;

(B) pass through any benefit, rebate, or payment the PBM receives for promoting a

drug that is more expensive than a drug prescribed;

(C) in the case that a PBM receives a payment or benefit for increasing volume of sales for a particular drug, class of drug, or brand of drug, disclose the payment or benefit with the covered entity; and

(D) disclose to covered entities all financial terms and arrangements between the PBM and a pharmaceutical drug company, including formulary management and drug-switch agreements, educational support, claims processing and pharmacy network fees that are charged from retail pharmacies, data sales fees, and other direct or indirect remunerations, including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in-kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers from any source, including manufacturers, pharmacies, enrollees, or any other person that would serve to decrease the costs incurred under the plan.

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

(3) DIRECT OR INDIRECT REMUNERATION.—For purposes of paragraph (1)(D), the term ''direct or indirect remuneration'' includes discounts, chargebacks or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in-kind, free or reduced-price services, grants, or other price concessions or similar benefits from manufacturers, pharmacies or similar entities obtained by an intermediary contracting organization with which the plan sponsor has contracted, regardless of whether the intermediary contracting organization retains all or a portion of the direct and indirect remuneration or passes the entire direct and indirect remuneration to the plan sponsor and regardless of the terms of the contract between

the plan sponsor and the intermediary contracting organization.

(d) CONFIDENTIALITY.—

(1) IN GENERAL.—A PBM may require covered entities to keep the information described in subsection (c)(4) confidential.

(2) RESTRICTIONS ON THE USE OF INFORMATION.—

(A) IN GENERAL.—Officers, employees, and contractors of the Department of Health and Human Services may use the information disclosed or obtained in accordance with the provisions of this Act only for the purposes of, and to the extent necessary in, carrying out this Act, including determination of payments, payment-related oversight, and program integrity activities.

(B) LIMITATIONS.—

(i) AUTHORITY OF THE OIG.—The restriction described in subparagraph (A) does not limit the authority of the Inspector General of the United States to fulfill the responsibilities of the Inspector General in accordance with applicable Federal law.

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

(e) AUDITS.—To ensure compliance with the requirements of this section, each covered entity shall conduct audits of the PBMs with which the covered entity contracts.

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

Title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) is amended by adding at the end the following new section:

''CERTIFICATION FOR OFF-LABEL PRESCRIBING OF CERTAIN DRUGS PRESCRIBED IN A NURSING HOME SETTING

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

''(b) DEFINITIONS.—In this section:

''(1) APPLICABLE DRUG.—The term 'applicable drug' means an atypical antipsychotic prescribed for use in a nursing home setting (as defined by the Secretary).

''(2) OFF-LABEL USE.—The term 'off-label use' means a use which has not been approved by the Food and Drug Administration.

''(3) MEDICALLY ACCEPTED INDICATION.—The term 'medically accepted indication' means the applicable drug is included in the compendia described in section 1861(t)(1) or is approved by a committee described in such section (or, in the case of an applicable drug that is a covered part D drug (as defined in section 1860D–2(e)), has the meaning given such term in paragraph (4) of such section 1860D–2(e)).

''(c) REGULATIONS.—The Secretary shall establish by regulation requirements that, effective not later than 1 year after the date of enactment of this section, physicians and practitioners use the form developed under subsection (a) to make the certification under such subsection with respect to an applicable drug prescribed by the physician or practitioner for an off-label use under this title. In order to carry out these requirements in a timely manner, the Secretary shall promulgate regulations that take

effect on an interim basis, after notice and pending opportunity for public comment.''.

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

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

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

''(P) An entity that is a PACE provider offering a PACE program under section 1894 and section 1934 of the Social Security Act.''; and

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

''(iii) ADDITIONAL MECHANISM.—The Secretary shall establish a mechanism to ensure that a manufacturer does not pay a duplicate discount with respect to a drug that is subject to an agreement under this section if the PACE program receives any rebate (including any negotiated price concessions) for the drug under part D of title XVIII of the Social Security Act. Such mechanism shall be similar to the mechanism established under clause (ii).''.

(b) REQUIREMENTS.—

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

''(9) PARTICIPATION IN 340B PROGRAM.—

''(A) IN GENERAL.—In the case of a PACE program that serves part D eligible individuals who are enrolled under such program, the PACE program agreement for such program shall require the PACE provider offering the program to participate in the drug discount program under section 340B of the Public Health Service Act for purposes of purchasing covered part D drugs with respect to qualified prescription drug coverage provided to such individuals.

''(B) ATTESTATION.—The Secretary may accept an attestation by a PACE provider, at the time of submitting a bid pursuant to section 1860D–21(f), as sufficient evidence of participation in the drug discount program under section 340B of the Public Health Service Act for purposes of subparagraph (A).

''(C) ENSURING TIMELY ACCESS TO COVERED OUTPATIENT DRUGS.—Nothing in this

paragraph shall prevent a PACE program from providing enrollees access to covered outpatient drugs (including covered part D drugs) through a retail community pharmacy (as defined in section 1927(k)(10)) that is not a contract pharmacy under the drug discount program under section 340B of the Public Health Service Act in the case where such access is necessary to ensure that such drugs are dispensed to enrollees on a timely basis.

''(D) DEFINITIONS.—In this paragraph:

''(i) COVERED OUTPATIENT DRUG.—The term 'covered outpatient drug' has the meaning given such term for purposes of section 340B of the Public Health Service Act.

''(ii) COVERED PART D DRUG.—The term 'covered part D drug' has the meaning given such term in section 1860D–2(e).

''(iii) PART D ELIGIBLE INDIVIDUAL.—The term 'part D eligible individual' has the meaning given such term in section 1860D–1(a)(3)(A).

''(iv) QUALIFIED PRESCRIPTION DRUG COVERAGE.—The term 'qualified prescrip-

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

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

''(9) PARTICIPATION IN 340B PROGRAM.—

''(A) IN GENERAL.—In the case of a PACE program that serves part D eligible individuals who are enrolled under such program, the PACE program agreement for such program shall require the PACE provider offering the program to participate in the drug discount program under section 340B of the Public Health Service Act for purposes of purchasing covered part D drugs with respect to qualified prescription drug coverage provided to such individuals.

''(B) ATTESTATION.—The Secretary may accept an attestation by a PACE provider, at the time of submitting a bid pursuant to section 1860D–21(f), as sufficient evidence of participation in the drug discount program under section 340B of the Public Health Service Act for purposes of subparagraph (A).

"(C) ENSURING TIMELY ACCESS TO COVERED OUTPATIENT DRUGS.—Nothing in this paragraph shall prevent a PACE program from providing enrollees access to covered outpatient drugs (including covered part D drugs) through a retail community pharmacy (as defined in section 1927(k)(10)) that is not a contract pharmacy under the drug discount program under section 340B of the Public Health Service Act in the case where such access is necessary to ensure that such drugs are dispensed to enrollees on a timely basis.

"(D) DEFINITIONS.—In this paragraph:

"(i) COVERED OUTPATIENT DRUG.—The term 'covered outpatient drug' has the meaning given such term for purposes of section 340B of the Public Health Service Act.

"(ii) COVERED PART D DRUG.—The term 'covered part D drug' has the meaning given such term in section 1860D–2(e).

"(iii) PART D ELIGIBLE INDIVIDUAL.—The term 'part D eligible individual' has the meaning given such term in section 1860D–1(a)(3)(A).

''(iv) QUALIFIED PRESCRIPTION DRUG COVERAGE.—The term 'qualified prescription drug coverage' has the meaning given such term in section 1860D–2(a).''.

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

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

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

''(4) PARTICIPATION IN 340B PROGRAM.—

''(A) INCLUSION OF SAVINGS IN BIDS SUBMITTED.—

''(i) DETERMINATION OF SAVINGS.—An organization offering prescription drug coverage under this subsection shall determine the estimated annual savings to the organization as a result of participation in the drug discount program under section 340B of the Public Health Service Act (as

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

''(ii) INCLUSION IN BIDS SUBMITTED.—The bid of an organization offering prescription drug coverage under this subsection shall reflect the estimated savings determined by the organization under clause (i) for the plan year involved, and shall take into account any additional costs to the organization as a result of the implementation and administration of such drug discount program during the plan year involved. Such bid shall include an attestation by the organization that such savings are reflected in the bid amount.

''(iii) CONSIDERATION OF APPLICABLE CEILING PRICES.—In making the determination under clause (i), the organization shall consider the applicable ceiling prices for covered outpatient drugs (using the access provided under section 340B(d)(1)(B)(iii) of the Public Health Service Act).

''(B) RECEIPT OF PERCENTAGE OF SAVINGS.—

"(i) IN GENERAL.—Subject to clause (ii), an organization offering prescription drug coverage under this subsection shall be eligible to receive from the Secretary an amount equal to 10 percent of the estimated annual savings to the Federal government (as determined by the Secretary under regulations promulgated under subparagraph (C)) to the organization as a result of participation in the drug discount program under section 340B of the Public Health Service Act (as described in sections 1894(e)(2)(C) and 1934(e)(2)(C)). In making the determination under the preceding sentence, the Secretary shall consider the determination of the organization under subparagraph (A)(i).

"(ii) REQUIREMENTS.—An organization shall only be eligible to receive the amount under clause (i) for the plan year involved if the organization—

"(I) submits to the Secretary an application in such form and manner, and containing such information, as the Secretary may specify; and

"(II) has in effect a plan approved by the Secretary for the use of any amounts received under such clause to—

"(aa) provide to enrollees enhanced formulary coverage, medication management, or disease management;

"(bb) invest in the development of the organization (including through the use of a significant proportion of the savings to invest in the development and use of qualified electronic health records (as defined in section 3000(13) of the Public Health Service Act) or other health information technology); or

"(cc) carry out other initiatives approved by the Secretary.

"(C) REGULATIONS.—The Secretary shall promulgate regulations to carry out this paragraph and sections 1894(e)(9) and 1934(e)(9).".

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

(d) NOT TREATED AS CHANGE IN LAW FOR PURPOSES OF DETERMINING MANUFACTURER COMPLIANCE.—Section 1927(a)(5) of the Social Security Act (42 U.S.C. 1396r–8(a)(5)) is amended—

(1) in subparagraph (D)—

(A) by striking ''AMENDMENTS.—In determining'' and inserting ''AMENDMENTS.—

''(i) IN GENERAL.—Subject to clause (ii), in determining''; and

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

''(ii) EXCEPTION.—The Secretary shall take into account the amendments made by section 9 of the Prescription Drug Cost Reduction Act for purposes of determining whether an agreement under subparagraph (A) meets the requirements of section 340B of the Public Health Service Act and an agreement under such subparagraph shall not be determined to meet such requirements if it does not meet the re-

quirements under such section with respect to covered outpatient drugs purchased by a covered entity described in subsection (a)(4)(P) of such section on or after the date that is 1 year after the date of enactment of such Act.''; and

(2) in subparagraph (E)—

(A) by striking ''COMPLIANCE.—A manufacturer'' and inserting ''COMPLIANCE.—

''(i) IN GENERAL.—Subject to clause (ii), a manufacturer''; and

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

''(ii) EXCEPTION.—The amendments made by section 9 of the Prescription Drug Cost Reduction Act shall not be treated as a legislative change for purposes of applying clause (i) and a manufacturer shall not be deemed to be in compliance with the requirements of this paragraph if the manufacturer has not entered into an agreement with the Secretary that meets the requirements under section 340B of the Public Health Service Act with respect to covered outpatient drugs purchased by a covered

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

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