

109<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# S. 1128

To amend title XIX of the Social Security Act to provide for increased rebates under the medicaid program for prescription drugs that are directly advertised to consumers, to require other Federal programs purchasing or reimbursing for such drugs to establish payment and reimbursement mechanisms that reduce the costs of those drugs, and for other purposes.

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IN THE SENATE OF THE UNITED STATES

MAY 26, 2005

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

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## A BILL

To amend title XIX of the Social Security Act to provide for increased rebates under the medicaid program for prescription drugs that are directly advertised to consumers, to require other Federal programs purchasing or reimbursing for such drugs to establish payment and reimbursement mechanisms that reduce the costs of those drugs, 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Pharmaceutical Adver-  
3 tising and Prudent Purchasing Act”.

4 **SEC. 2. INCREASED REBATES UNDER THE MEDICAID PRO-**  
5 **GRAM FOR PRESCRIPTION DRUGS DIRECTLY**  
6 **ADVERTISED TO CONSUMERS.**

7 (a) IN GENERAL.—Section 1927(b) of the Social Se-  
8 curity Act (42 U.S.C. 1396r–8(b)) is amended by adding  
9 at the end the following:

10 “(5) INCREASE IN AMOUNT OF REBATE FOR  
11 COVERED OUTPATIENT DRUGS DIRECTLY ADVER-  
12 TISED TO CONSUMERS.—

13 “(A) IN GENERAL.—A rebate agreement  
14 under this subsection shall provide for an in-  
15 crease in the amount of the rebate determined  
16 under subsection (c) with respect to each cov-  
17 ered outpatient drug of a manufacturer for  
18 which payment is made under the State pro-  
19 gram under this title if the manufacturer of  
20 such drug fails to certify to the Secretary that  
21 the drug was not directly advertised to con-  
22 sumers during the rebate period applicable to  
23 such agreement.

24 “(B) ADJUSTMENT OF REBATE FOR-  
25 MULA.—

1           “(i) IN GENERAL.—Not later than  
2           180 days after the date of enactment of  
3           this paragraph, the Secretary shall deter-  
4           mine appropriate adjustments to make to  
5           the formula used to calculate the amount  
6           of a rebate under subsection (c) to deter-  
7           mine the increased amount of the rebate  
8           required under subparagraph (A), includ-  
9           ing, to the extent the Secretary determines  
10          appropriate, to the application of the aver-  
11          age manufacturer price and best price in  
12          such formula.

13          “(ii) REQUIREMENTS.—In deter-  
14          mining the adjustments required under  
15          clause (i), the Secretary shall—

16                 “(I) take into account the in-  
17                 creased costs to the State program es-  
18                 tablished under this title resulting  
19                 from the purchase of covered out-  
20                 patient drugs that are directly adver-  
21                 tised to consumers; and

22                 “(II) consult with manufacturers.

23          “(C) DEFINITION OF DIRECTLY ADVER-  
24          TISED TO CONSUMERS.—In this section, the  
25          term ‘directly advertised to consumers’ means a

1 reminder ad or product claim regarding a cov-  
2 ered outpatient drug that is disseminated  
3 through radio, television, or other electronic  
4 media, print media, or outdoor advertising.”.

5 (b) EFFECTIVE DATE.—The amendment made by  
6 this section applies to rebate agreements entered into or  
7 renewed under section 1927 of the Social Security Act (42  
8 U.S.C. 1396r–8) on or after the date that is 180 days  
9 after the date of enactment of this Act.

10 **SEC. 3. REDUCED PAYMENT AND REIMBURSEMENT MECHA-**  
11 **NISMS FOR OTHER FEDERAL PROGRAMS**  
12 **THAT PURCHASE OR PROVIDE REIMBURSE-**  
13 **MENT FOR PRESCRIPTION DRUGS THAT ARE**  
14 **DIRECTLY ADVERTISED TO CONSUMERS.**

15 (a) IN GENERAL.—Not later than 180 days after the  
16 date of enactment of this Act, the Secretary of Health and  
17 Human Services and the Secretary of Veterans Affairs  
18 each shall develop and implement procedures under which  
19 any master agreement, pricing agreement, or contract en-  
20 tered into on or after that date for the procurement or  
21 purchase of a covered drug or a covered outpatient drug  
22 by a Federal agency or reimbursement program described  
23 in subsection (b) shall provide that the agency or program  
24 shall pay a negotiated reduced price for such drug unless  
25 the manufacturer has certified to the head of the agency

1 or program that the drug was not directly advertised to  
2 consumers during the 12-month period preceding the date  
3 of such procurement or purchase.

4 (b) FEDERAL AGENCIES AND PROGRAMS DE-  
5 SCRIBED.—For purposes of subsection (a), the Federal  
6 agencies and reimbursement programs described in this  
7 subsection are the following:

8 (1) The Public Health Service, including health-  
9 related programs administered by the Indian Health  
10 Service, and health-related programs funded under  
11 the Public Health Service Act, including the drug  
12 pricing agreement program established under section  
13 340B of such Act (42 U.S.C. 256b).

14 (2) The Department of Veterans Affairs and  
15 the program of medical care furnished by the Sec-  
16 retary of Veterans Affairs.

17 (3) The Department of Defense and the De-  
18 fense Health Program.

19 (c) DEFINITIONS.—In this section:

20 (1) COVERED DRUG.—The term “covered drug”  
21 has the meaning given that term in section  
22 8126(h)(2) of title 38, United States Code.

23 (2) COVERED OUTPATIENT DRUG.—The term  
24 “covered outpatient drug” has the meaning given

1 that term in section 1927(k)(2) of the Social Secu-  
2 rity Act (42 U.S.C. 1396r–8(k)(2)).

3 (3) DIRECTLY ADVERTISED TO CONSUMERS.—

4 The term “directly advertised to consumers” means  
5 a reminder ad or product claim regarding a covered  
6 drug or a covered outpatient drug that is dissemi-  
7 nated through radio, television, or other electronic  
8 media, print media, or outdoor advertising.

9 (4) MANUFACTURER.—The term “manufac-  
10 turer” has the meaning given that term in section  
11 8126(h)(4) of title 38, United States Code, and sec-  
12 tion 1927(k)(5) of the Social Security Act (42  
13 U.S.C. 1936r–8(k)(5)).

14 (d) CONFORMING AMENDMENTS.—

15 (1) PRESCRIPTION DRUGS PURCHASED BY COV-  
16 ERED ENTITIES UNDER AGREEMENTS ENTERED  
17 INTO UNDER THE PUBLIC HEALTH SERVICE ACT.—  
18 Section 340B(a) of the Public Health Service Act  
19 (42 U.S.C. 256b(a)) is amended—

20 (A) in paragraph (1), by inserting “or re-  
21 quired under paragraph (11)” after “as pro-  
22 vided by the Secretary”; and

23 (B) by adding at the end the following:

1           “(11) REDUCED NEGOTIATED PRICE FOR COV-  
2           ERED DRUGS ADVERTISED DIRECTLY TO CON-  
3           SUMERS.—

4                   “(A) IN GENERAL.—An agreement entered  
5           into under paragraph (1) shall provide that  
6           with respect to each covered drug of the manu-  
7           facturer that is purchased by a covered entity,  
8           the price charged shall not exceed the reduced  
9           negotiated price for that drug in accordance  
10          with the procedures established under section  
11          3(a) of the Pharmaceutical Advertising and  
12          Prudent Purchasing Act if the manufacturer  
13          fails to certify to the Secretary that the drug  
14          was not directly advertised to consumers during  
15          the 12-month period preceding the date of such  
16          purchase.

17                   “(B) DEFINITION OF DIRECTLY ADVER-  
18           TISED TO CONSUMERS.—In subparagraph (A),  
19           the term ‘directly advertised to consumers’  
20           means a reminder ad or product claim regard-  
21           ing a covered outpatient drug that is dissemi-  
22           nated through radio, television, or other elec-  
23           tronic media, print media, or outdoor adver-  
24           tising.”.

1           (2) PROCUREMENT OF PRESCRIPTION DRUGS  
2 BY THE DEPARTMENT OF VETERANS AFFAIRS, DE-  
3 PARTMENT OF DEFENSE, THE PUBLIC HEALTH  
4 SERVICE (INCLUDING THE INDIAN HEALTH SERVICE)  
5 AND THE COAST GUARD.—Section 8126 of title 38,  
6 United States Code, is amended—

7           (A) in subsection (a)—

8                 (i) in paragraph (3), by striking  
9 “and” at the end;

10                (ii) by redesignating paragraph (4) as  
11 paragraph (5);

12                (iii) in paragraph (5) (as redesignated  
13 by clause (ii)), by striking “and (3)” and  
14 inserting “(3), and (4)”; and

15                (iv) by inserting after paragraph (3),  
16 the following:

17           “(4) with respect to each covered drug of the  
18 manufacturer that is procured by a Federal agency  
19 described in subsection (b) under depot contracting  
20 systems, a national contract entered into by the Sec-  
21 retary, or under the Federal Supply Schedule, the  
22 price charged shall not exceed the reduced nego-  
23 tiated price for that drug in accordance with the  
24 procedures established under section 3(a) of the  
25 Pharmaceutical Advertising and Prudent Purchasing

1 Act if the manufacturer fails to certify to the Sec-  
 2 retary or the head of the Federal agency involved  
 3 that the drug was not directly advertised to con-  
 4 sumers during the 12-month period preceding the  
 5 date of such procurement;” and

6 (B) in subsection (h), by adding at the end  
 7 the following:

8 “(7) DIRECTLY ADVERTISED TO CONSUMERS.—  
 9 The term ‘directly advertised to consumers’ means a  
 10 reminder ad or product claim regarding a covered  
 11 drug that is disseminated through radio, television,  
 12 or other electronic media, print media, or outdoor  
 13 advertising.”.

14 (e) EFFECTIVE DATE.—The amendments made by  
 15 this section apply to master agreements, pricing agree-  
 16 ments, and contracts entered into or renewed on or after  
 17 the date that is 180 days after the date of enactment of  
 18 this Act.

19 **SEC. 4. REPORT TO CONGRESS ON STRATEGIES TO REDUCE**  
 20 **THE COST OF PRESCRIPTION DRUGS COV-**  
 21 **ERED UNDER MEDICARE AND OTHER FED-**  
 22 **ERAL PROGRAMS THAT ARE DIRECTLY AD-**  
 23 **VERTISED TO CONSUMERS.**

24 (a) IN GENERAL.—Not later than January 1, 2007,  
 25 the Secretary of Health and Human Services, in consulta-

1 tion with the Secretary of Veterans Affairs, shall submit  
2 a report to Congress that contains the following informa-  
3 tion:

4 (1) The percentage of costs for prescription  
5 drugs that are directly advertised to consumers that  
6 are passed on to Federal agencies and programs  
7 that purchase or provide reimbursement for such  
8 drugs.

9 (2) The 25 most frequently prescribed drugs  
10 that are directly advertised to consumers and are  
11 purchased or reimbursed by Federal agencies and  
12 programs.

13 (3) The 25 most costly prescription drugs that  
14 are directly advertised to consumers and are pur-  
15 chased or reimbursed by Federal agencies and pro-  
16 grams.

17 (4) The aggregate amount spent by manufac-  
18 turers of prescription drugs—

19 (A) to directly advertise to consumers; and

20 (B) for the 25 most costly prescription  
21 drugs that are directly advertised to consumers.

22 (5) Mechanisms for Federal agencies and pro-  
23 grams to share information concerning—

24 (A) which prescription drugs are directly  
25 advertised to consumers;

1 (B) the costs to Federal agencies and pro-  
2 grams of such drugs; and

3 (C) utilization, cost, and reimbursement  
4 data regarding the purchase of such drugs, sep-  
5 arately identified with respect to the medicare  
6 program and other Federal agencies and pro-  
7 grams, and disaggregated for age cohorts, gen-  
8 der, and diagnoses of the individuals using such  
9 drugs.

10 (6) Recommendations for legislative or adminis-  
11 trative changes or alternative strategies, separately  
12 identified with respect to the medicare program and  
13 other Federal agencies and programs, to ensure that  
14 Federal payments for prescription drugs are reduced  
15 for prescription drugs directly advertised to con-  
16 sumers.

17 (7) Strategies to ensure that prescription drug  
18 utilization under Federal agencies and programs is  
19 based on health needs.

20 (8) Such other recommendations for legislation  
21 or administrative action as the Secretary determines  
22 to be appropriate.

23 (b) DEFINITIONS.—In this section:

24 (1) DIRECTLY ADVERTISED TO CONSUMERS.—

25 The term “directly advertised to consumers” has the

1 meaning given that term in section 1927(b)(5)(C) of  
2 the Social Security Act (as added by section 2(a)).

3 (2) FEDERAL AGENCY AND PROGRAM.—The  
4 term “Federal agency and program” means the Fed-  
5 eral agencies and programs described in section 3(b)  
6 and includes the medicare program established  
7 under title XVIII of the Social Security Act (42  
8 U.S.C. 1395 et seq.).

9 (3) MANUFACTURER.—The term “manufac-  
10 turer” has the meaning given that term in section  
11 8126(h)(4) of title 38, United States Code, and sec-  
12 tion 1927(k)(5) of the Social Security Act (42  
13 U.S.C. 1396r–8(k)(5)).

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