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(Original Signature of Member)

112TH CONGRESS
1ST SESSION

H. R.

To amend section 340B of the Public Health Service Act to improve the provision of discounts on drug purchases for certain safety net providers.

IN THE HOUSE OF REPRESENTATIVES

Mrs. MCMORRIS RODGERS (for herself, Mr. RUSH, Mrs. EMERSON, Ms. BROWN of Florida, Mr. OWENS, Mr. CLARKE of Michigan, and [see ATTACHED LIST of cosponsors]) introduced the following bill; which was referred to the Committee on _____

A BILL

To amend section 340B of the Public Health Service Act to improve the provision of discounts on drug purchases for certain safety net providers.

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 “340B Program Im-
5 provement Act”.

1 **SEC. 2. EXTENSION OF DISCOUNTS TO INPATIENT DRUGS.**

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

4 (1) in subsection (a)—

5 (A) in paragraphs (1), (2), and (5), by
6 striking “covered outpatient drug” each place
7 such term appears and inserting “covered
8 drug”; and

9 (B) in paragraphs (1), (7), and (9), by
10 striking “covered outpatient drugs” each place
11 such term appears and inserting “covered
12 drugs”;

13 (2) in subsection (b)(2)(B) by striking “para-
14 graph (3)(A)” and inserting “paragraph (3)”; and

15 (3) in subsection (d), by striking “covered out-
16 patient drugs” each place such term appears and in-
17 serting “covered drugs”.

18 (b) MEDICAID CREDITS ON INPATIENT DRUGS.—
19 Section 340B of the Public Health Service Act (42 U.S.C.
20 256b) is amended by inserting after subsection (b) the fol-
21 lowing new subsection:

22 “(c) MEDICAID CREDITS ON INPATIENT DRUGS.—

23 “(1) IN GENERAL.—For each cost reporting pe-
24 riod, based on the most recently filed Medicare cost
25 report under title XVIII of the Social Security Act
26 and subject to paragraph (5), a hospital described in

1 subparagraph (L), (M), (N), or (O) of subsection
2 (a)(4) and enrolled to participate in the drug dis-
3 count program under this section shall provide to
4 each State that has a plan for medical assistance
5 under title XIX of such Act and that makes pay-
6 ment to such hospital for covered drugs provided to
7 Medicaid recipients for inpatient use, a credit on the
8 estimated annual purchases by such hospital of such
9 covered drugs provided to such Medicaid recipients.

10 “(2) AMOUNT OF CREDIT.—

11 “(A) IN GENERAL.—The credit described
12 in paragraph (1), with respect to a hospital and
13 cost reporting period described in such para-
14 graph shall be equal to—

15 “(i) the product of—

16 “(I) the sum of the annual credit
17 amounts (described in subparagraph
18 (B)) calculated under subparagraph
19 (B)(i) for each dosage form and
20 strength of each covered drug pur-
21 chased by the hospital during the cost
22 reporting period; and

23 “(II) the estimated percentage of
24 the purchases of covered drugs by the
25 hospital during such period attrib-

1 utable to Medicaid recipients for inpa-
2 tient use, as determined in accordance
3 with subparagraph (D); and

4 “(ii) subject to paragraph (3)(D), re-
5 duced by the amount by which the Med-
6 icaid inpatient reimbursement (as defined
7 in subparagraph (E)(ii)) of the hospital for
8 such period was reduced as a result of par-
9 ticipation in the drug discount program
10 under this section during such period by
11 the hospital, as determined in accordance
12 with subparagraph (E).

13 “(B) ANNUAL CREDIT AMOUNTS.—For
14 purposes of subparagraph (A)(i)(I), an annual
15 credit amount, with respect to a covered drug
16 purchased by a hospital described in paragraph
17 (1) during a cost reporting period of the hos-
18 pital—

19 “(i) is equal to the sum of the quar-
20 terly credit amounts calculated under sub-
21 paragraph (C)(i), for each of the 4 quar-
22 ters of the cost reporting period for such
23 covered drug; and

1 “(ii) shall be calculated for each dos-
2 age form and strength of such covered
3 drug.

4 “(C) QUARTERLY CREDIT AMOUNTS.—For
5 purposes of subparagraph (B)(ii), a quarterly
6 credit amount, with respect to a covered drug
7 purchased by a hospital described in paragraph
8 (1) during a quarter of the cost reporting pe-
9 riod of the hospital—

10 “(i) is equal to the product of—

11 “(I) the total number of units of
12 each dosage form and strength of
13 such covered drug purchased by the
14 hospital during such quarter;

15 “(II) the average manufacturer
16 price of the covered drug (for the unit
17 of the dosage form and strength in-
18 volved) during such quarter; and

19 “(III) half of the rebate percent-
20 age for the covered drug, as defined in
21 subsection (a)(2); and

22 “(ii) shall be calculated for—

23 “(I) each dosage form and
24 strength of the covered drug pur-
25 chased by the hospital; and

1 “(II) each of the 4 quarters of
2 such cost reporting period.

3 “(D) PERCENTAGE OF DRUG PURCHASES
4 ATTRIBUTABLE TO MEDICAID RECIPIENTS FOR
5 IMPATIENT USE.—For purposes of subpara-
6 graph (A)(i)(II), the estimated percentage of
7 the drug purchases of the hospital attributable
8 to Medicaid recipients for inpatient use shall be
9 equal to the Medicaid inpatient drug charges as
10 reported on the most recently filed Medicare
11 cost report of the hospital, divided by the total
12 drug charges reported on the cost report.

13 “(E) CREDIT OFFSET.—

14 “(i) IN GENERAL.—For purposes of
15 subparagraph (A)(ii), the amount by which
16 the Medicaid inpatient reimbursement of a
17 hospital, with respect to a cost reporting
18 period, is reduced as a result of the partici-
19 pation in the drug discount program under
20 this section by the hospital shall be com-
21 puted as the difference between—

22 “(I) the Medicaid inpatient reim-
23 bursement that would have otherwise
24 been payable to the hospital for the
25 cost reporting period if the hospital

1 did not participate in such drug dis-
2 count program; and

3 “(II) the actual Medicaid inpa-
4 tient reimbursement payable to the
5 hospital for the cost reporting period.

6 “(ii) MEDICAID INPATIENT REIM-
7 BURSEMENT DEFINED.—For purposes of
8 this subsection, the term ‘Medicaid inpa-
9 tient reimbursement’ means the total pay-
10 ments received by the hospital under the
11 State plan under title XIX of the Social
12 Security Act for providing inpatient serv-
13 ices to Medicaid recipients.

14 “(3) REQUIREMENTS.—

15 “(A) IN GENERAL.—A hospital shall not be
16 required to provide a credit under paragraph
17 (1) to a State unless, not later than 30 days
18 after receiving the information described in sub-
19 paragraph (B), the State calculates in accord-
20 ance with paragraph (2) the amount of the
21 credit owed by the hospital under paragraph (1)
22 and provides the hospital with both the amount
23 of such credit so owed and an explanation of
24 how the State calculated such credit.

1 “(B) HOSPITAL PROVISION OF INFORMA-
2 TION.—Not later than 30 days after the date of
3 the filing of the most recently filed Medicare
4 cost report of a hospital described in paragraph
5 (1), the hospital shall provide the State involved
6 with the information described in subpara-
7 graphs (C)(i)(I) and (D) of paragraph (2).
8 With respect to each covered drug purchased
9 during the cost reporting period, the hospital
10 shall provide the National Drug Code, date of
11 purchase, and the number of units purchased.
12 Submission of such information shall not be re-
13 quired if a covered drug has not been assigned
14 a National Drug Code at the time of purchase.

15 “(C) ACCESS TO AMP AND REBATE
16 DATA.—The Secretary shall establish a system
17 for giving States access to the information nec-
18 essary for them to calculate credits under para-
19 graph (2), with respect to covered drugs, in-
20 cluding the average manufacturer price and re-
21 bate percentage for such covered drugs.

22 “(D) CREDIT OFFSET.—Paragraph
23 (2)(A)(ii) shall be applied, with respect to a
24 credit owed by a hospital under paragraph (1),
25 only if, not later than 30 days after filing the

1 most recent Medicare cost report, the hospital
2 submits to the State involved—

3 “(i) a request for the State to apply
4 such paragraph and to calculate the
5 amount described in such paragraph in ac-
6 cordance with paragraph (2)(E); and

7 “(ii) the data needed by the State to
8 determine the amount of the Medicaid in-
9 patient reimbursement described in para-
10 graph (2)(E)(i)(I) for such hospital.

11 “(E) DISPUTES.—A State and hospital de-
12 scribed in paragraph (1) shall have access to
13 the same State dispute resolution procedures
14 and system applicable to Medicaid reimburse-
15 ment matters under title XIX of the Social Se-
16 curity Act.

17 “(4) PAYMENT DEADLINE.—A hospital shall
18 provide to a State the credits owed by such hospital
19 under paragraph (1) not later than 60 days after
20 the hospital receives the information described in
21 paragraph (3)(A).

22 “(5) OPT OUT.—A hospital shall not be re-
23 quired to provide a credit under paragraph (1) to a
24 State if the hospital and State agree to an alter-
25 native arrangement.

1 “(6) OFFSET AGAINST MEDICAL ASSISTANCE.—
2 Amounts received by a State under this subsection
3 shall be considered to be a reduction in the amount
4 expended under the State plan for medical assist-
5 ance for purposes of section 1903(a)(1) of the Social
6 Security Act.

7 “(7) MEDICAID RECIPIENT DEFINED.—For
8 purposes of this subsection, the term ‘Medicaid re-
9 cipient’ means, with respect to a State, an individual
10 who receives benefits under the State plan under
11 title XIX of the Social Security Act.”.

12 (c) CONFORMING AMENDMENTS.—Section 1927 of
13 the Social Security Act (42 U.S.C. 1396r–8) is amended—

14 (1) in subsection (a)(5)—

15 (A) in subparagraph (A), by striking “cov-
16 ered outpatient drugs” and inserting “covered
17 drugs (as defined in section 340B(b)(2) of the
18 Public Health Service Act)”; and

19 (B) by striking subparagraphs (D) and
20 (E); and

21 (2) in subsection (c)(1)(C)(i)—

22 (A) by redesignating subclauses (II)
23 through (VI) as subclauses (III) through (VII),
24 respectively; and

1 (B) by inserting after subclause (I) the fol-
2 lowing:

3 “(II) any prices charged for a
4 covered drug, as defined in section
5 340B(b)(2) of the Public Health Serv-
6 ice Act;”.

7 **SEC. 3. PROHIBITION AGAINST DUPLICATE DISCOUNTS**
8 **FOR PHYSICIAN ADMINISTERED DRUGS.**

9 Section 340B(a)(5)(A) of the Public Health Service
10 Act (42 U.S.C. 256b) is amended by adding at the end
11 the following:

12 “(iii) PHYSICIAN ADMINISTERED
13 DRUGS.—A hospital described in subpara-
14 graph (L), (M), (N), or (O) of paragraph
15 (4) shall not be required under section
16 1927(a)(7) of the Social Security Act to
17 report National Drug Code numbers for
18 drugs administered by a physician (or
19 under a physician’s supervision) if the
20 State is precluded from seeking a rebate
21 on such drugs because such drugs were
22 purchased at a discount under this section.
23 Nothing in this clause shall relieve a hos-
24 pital of its obligation to submit National

1 Drug Codes in accordance with subsection
2 (c)(3)(B).”.

3 **SEC. 4. CONTINUED INCLUSION OF ORPHAN DRUGS IN DEF-**
4 **INITION OF COVERED OUTPATIENT DRUGS;**
5 **TECHNICAL AMENDMENT.**

6 (a) IN GENERAL.—Section 340B of the Public
7 Health Service Act (42 U.S.C. 256b) is amended by strik-
8 ing subsection (e).

9 (b) EFFECTIVE DATE.—The amendment made by
10 subsection (a) shall apply to drugs purchased on or after
11 March 30, 2010.

12 **SEC. 5. APPLICATION OF RULES FOR DETERMINING PRO-**
13 **VIDER-BASED STATUS FOR CERTAIN ENTI-**
14 **TIES.**

15 Notwithstanding any other provision of law, in mak-
16 ing determinations of provider-based status under title
17 XVIII of the Social Security Act, the facility or organiza-
18 tion shall be treated as satisfying any requirements and
19 standards for geographic location in relation to a hospital
20 or a critical access hospital if the facility or organization
21 is described in subparagraph (L), (M), (N), or (O) of sec-
22 tion 340B(a)(4) of the Public Health Service Act (42
23 U.S.C. 256b(a)(4)).