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(Original Signature of Member)

110TH CONGRESS
1ST SESSION

H. R.

To amend title XIX of the Social Security Act to ensure and foster continued beneficiary access to generic drugs under the Medicaid program by setting pharmacy reimbursement based on retail acquisition cost and to promote the use of generic drugs.

IN THE HOUSE OF REPRESENTATIVES

Mrs. BOYDA of Kansas (for herself, Mr. WEINER, Mrs. EMERSON, Mr. ADERHOLT, Mr. ALEXANDER, Mr. BERRY, Mr. BONNER, Mr. BOREN, Mr. BOUCHER, Mr. BOUSTANY, Mr. BRALEY of Iowa, Mr. CARNEY, Mr. CUMMINGS, Mr. DAVID DAVIS of Tennessee, Mr. DAVIS of Kentucky, Mr. ETHERIDGE, Mr. FARR, Mr. GORDON of Tennessee, Mr. HIGGINS, Mr. JONES of North Carolina, Mr. LOBIONDO, Mr. LOEBSACK, Mr. MOORE of Kansas, Mr. MORAN of Kansas, Mr. ORTIZ, Mr. ROGERS of Alabama, Mr. ROSS, Mr. SKELTON, Mr. TIAHRT, and Mr. WALZ of Minnesota) introduced the following bill; which was referred to the Committee on

A BILL

To amend title XIX of the Social Security Act to ensure and foster continued beneficiary access to generic drugs under the Medicaid program by setting pharmacy reimbursement based on retail acquisition cost and to promote the use of generic drugs.

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 “Saving Our Commu-
3 nity Pharmacies Act of 2007”.

4 **SEC. 2. USING MEDIAN RETAIL ACQUISITION COST AS**
5 **BASIS FOR MEDICAID REIMBURSEMENT LIM-**
6 **ITS ON GENERIC DRUGS.**

7 (a) IN GENERAL.—Subsection (e) of section 1927 of
8 the Social Security Act (42 U.S.C. 1396r-8) is amended
9 by striking paragraph (5) and inserting the following:

10 “(5) APPLICATION OF FEDERAL UPPER PAY-
11 MENT LIMITS.—

12 “(A) CONTINUED USE OF AWP.— Effective
13 January 1, 2007, and until subparagraph (B) is
14 in effect, in applying the Federal upper reim-
15 bursement limit under paragraph (4) and sec-
16 tion 447.332(b) of title 42 of the Code of Fed-
17 eral Regulations, the Secretary shall continue to
18 apply the methodology in effect before the date
19 of the enactment of the Deficit Reduction Act
20 of 2005.

21 “(B) USE OF MEDIAN RETAIL ACQUISITION
22 COST.— Effective on the first day of the second
23 quarter that begins after the date of the enact-
24 ment of the Saving Our Community Phar-
25 macies Act of 2007, in applying the Federal
26 upper reimbursement limit under paragraph (4)

1 and section 447.332(b) of title 42 of the Code
2 of Federal Regulations (as in effect but for sub-
3 paragraph (A)), the Secretary shall substitute
4 the median retail acquisition cost (as computed
5 under subparagraph (C)) for the published
6 price.

7 “(C) COMPUTATION OF MEDIAN RETAIL
8 ACQUISITION COST.—

9 “(i) SMOOTHING AND TRANSITIONS.—
10 Except as otherwise provided in this sub-
11 paragraph, the Secretary shall calculate
12 the median retail acquisition cost for a
13 multiple source drug subject to a Federal
14 upper limit for months in a calendar quar-
15 ter by computing the median of the retail
16 acquisition costs (as defined in subsection
17 (k)(10)) over the 4-calendar-quarter period
18 ending with the second preceding calendar
19 quarter.

20 “(ii) LIMITATION ON SALES TO BE
21 COUNTED.— In computing the median re-
22 tail acquisition cost for a drug, the Sec-
23 retary shall not take into account sales
24 other than sales to community retail phar-
25 macies and shall not include the following;

1 “(I) Sales to mail order facilities.

2 “(II) Prices paid under a State
3 supplemental program, State only pro-
4 gram, or a State Pharmacy Assistance
5 Programs (SPAP).

6 “(iii) TRANSITION FOR FIRST IMPLE-
7 MENTATION.—For the first 4 calendar
8 quarters in which subparagraph (B) is in
9 effect, subject to clause (iv), in calculating
10 the median retail acquisition cost for all
11 drugs the Secretary shall only use the re-
12 tail acquisition costs for those quarters be-
13 ginning with the last calendar quarter that
14 began before the date of the enactment of
15 this paragraph for which data are released.

16 “(iv) TRANSITION FOR DRUGS NEWLY
17 QUALIFYING AS MULTIPLE SOURCE.—In
18 the case of a drug product for the first
19 four calendar quarters in which it qualifies
20 as a multiple source drug, in calculating
21 the median retail acquisition cost for the
22 drug the Secretary shall only use the retail
23 acquisition costs for the drug beginning
24 with the first such quarter for which data
25 are collected.”.

1 (b) DEFINITION OF RETAIL ACQUISITION COST AND
2 RELATED DEFINITIONS.—Subsection (k) of such section
3 is amended by adding at the end the following new para-
4 graph:

5 “(10) RETAIL ACQUISITION COST AND RELATED
6 DEFINITIONS.—

7 “(A) RETAIL ACQUISITION COST.—The
8 term ‘retail acquisition cost’ means, for a mul-
9 tiple source drug furnished, the costs of com-
10 munity retail pharmacies (as defined in sub-
11 paragraph (D)) to obtain the drug, as deter-
12 mined under subsection (f)(5).

13 “(B) ITEMS NOT INCLUDED IN RETAIL AC-
14 QUISITION COST.—In computing the retail ac-
15 quisition costs for a drug, the following shall
16 not be taken into account:

17 “(i) Discounts, rebates, and price con-
18 cessions to pharmacy benefit managers.

19 “(ii) Non-contingent free goods.

20 “(iii) Patient assistance programs,
21 such as specialty services for cancer treat-
22 ment.

23 “(iv) Administrative service agree-
24 ments.

25 “(v) Inventory management fees.

1 “(vi) Fee-for-service agreements to
2 wholesalers.

3 “(vii) Adjustments that reduce the ac-
4 tual price realized, except to the extent
5 that they are not reflective of purchasing
6 costs of retail pharmacies.

7 “(viii) Costs of other classes of trade
8 not reflective of retail pharmacy pur-
9 chasing costs.

10 “(ix) Prompt pay discounts extended
11 to retail community pharmacies.

12 “(C) ITEMS TAKEN INTO ACCOUNT IN DE-
13 TERMINING RETAIL ACQUISITION COST.— In
14 computing the retail acquisition cost for a drug,
15 the Secretary shall take into account the fol-
16 lowing:

17 “(i) Volume (or comparable discounts)
18 discounts, chargebacks, and allowances for
19 free goods contingent on purchase require-
20 ments, to the extent actually paid or cred-
21 ited to the retail pharmacy. Discounts that
22 may be paid in a calendar quarter for an
23 aggregate purchase of generic drugs, ap-
24 plied to each drug in proportion to the per-
25 centage purchased.

1 “(ii) An estimate of the rebates and
2 discounts that may be earned by retail
3 community pharmacies but not credited in
4 the time period in which the average retail
5 acquisition cost is calculated for each drug
6 in the survey, as determined in accordance
7 with a methodology specified by the survey
8 contractor after consultation with the af-
9 fected stakeholders.

10 “(iii) In the event of a reduction in
11 the acquisition price of a drug by a manu-
12 facturer where that manufacturer issues a
13 credit to the pharmacy to lower the cost of
14 existing inventory to the new acquisition
15 price, such credit shall be applied to the
16 existing inventory, acquired at the higher
17 cost, to lower the cost basis of that exist-
18 ing inventory and such lower cost basis
19 shall be the acquisition price for such in-
20 ventory in any price reported.

21 “(iv) With respect to drugs dispensed
22 by pharmacies that own and operate their
23 own warehouse distribution systems, inso-
24 far as the retail acquisition costs takes into
25 account the costs associated with the own-

1 ership and operation of such distribution
2 system, such costs shall be a fixed percent-
3 age of the average wholesaler markup, as
4 promulgated each year by the Secretary.

5 “(D) COMMUNITY RETAIL PHARMACY.—

6 The term ‘community retail pharmacy’ means a
7 traditional independent, chain, mass merchan-
8 dise, or supermarket pharmacy.

9 “(E) PHARMACY BENEFITS MANAGER.—

10 The term ‘pharmacy benefits manager’ means
11 an entity that contracts with a managed care
12 organization, self-insured company, or govern-
13 ment program to provide a range of pharmacy
14 management benefit services, including phar-
15 macy network management, drug utilization re-
16 view, outcomes management, and disease man-
17 agement.

18 “(F) WIDELY AVAILABLE.—The term
19 ‘widely available’ means, with respect to a mul-
20 tiple source drug, that the drug is available for
21 purchase by retail community pharmacies
22 throughout the nation from at least two na-
23 tional wholesalers.”.

1 (c) SURVEYS OF COMMUNITY RETAIL PRICES.—Sub-
2 section (f) of such section is amended by adding at the
3 end the following new paragraph:

4 “(5) SURVEYS FOR DETERMINING COMMUNITY
5 RETAIL PRICES FOR MULTIPLE SOURCE DRUGS.—
6 The following rules apply to the determination of re-
7 tail acquisition costs for multiple source drugs for
8 purposes of computing the median retail acquisition
9 cost under subsection (e)(5):

10 “(A) IN GENERAL.—The Secretary shall
11 conduct national surveys on a quarterly basis of
12 community retail pharmacies using the criteria
13 described in such subsection to determine retail
14 acquisition costs for all multiple source drugs.
15 The first such survey shall be for the calendar
16 quarter in which Saving Our Community Phar-
17 macies Act of 2007 is enacted.

18 “(B) SAMPLE.—Each such survey shall
19 consist of a randomly selected sample that—

20 “(i) represents at least 5 percent of
21 the community retail pharmacies; and

22 “(ii) contains a representative per-
23 centage of business among the types of
24 community retail pharmacies, including

1 independent, chain, mass merchandise, and
2 supermarket pharmacies.

3 “(C) SURVEY INFORMATION.—The cost
4 surveys shall include surveys of the elements
5 used in computing retail acquisition costs, in-
6 cluding those items excluded (or included) in
7 computing such costs under subparagraphs (B)
8 and (C) of subsection (k)(10). In completing
9 the cost surveys and disclosing other informa-
10 tion under this section, retail community phar-
11 macies may make reasonable assumptions and
12 interpretations that are reasonably consistent
13 with the terms of this section.

14 “(D) TREATMENT OF PHARMACIES UNDER
15 COMMON OWNERSHIP OR PURCHASING AR-
16 RANGEMENTS.—In the case of retail community
17 pharmacies that purchase a multiple source
18 drug through common ownership, management,
19 or other arrangements, such pharmacies shall
20 report the average price paid for the multiple
21 source drug across all pharmacies operating
22 under such common ownership, management, or
23 arrangement.

24 “(E) CONFIDENTIALITY.—The information
25 disclosed in response to surveys under this

1 paragraph is confidential and the Secretary (or
2 any contractor therewith) shall not disclose
3 such information in a form which discloses the
4 identity of a specific pharmacy or company, or
5 the retail acquisition costs for multiple source
6 drugs of such a pharmacy or company, ex-
7 cept—

8 “(i) as the Secretary determines to be
9 necessary to carry out this section;

10 “(ii) to permit the Comptroller Gen-
11 eral to review the information provided;

12 “(iii) to permit the Director of the
13 Congressional Budget Office to review the
14 information provided; and

15 “(iv) to the Secretary to disclose
16 (through a website accessible to the public)
17 median retail acquisition costs.

18 The Secretary shall post on a public Federal
19 website for the Medicaid program (and other-
20 wise make available to States) the median retail
21 acquisition costs for multiple source drugs.

22 “(F) CONTRACTOR BIDDING.—The Sec-
23 retary shall provide for surveys under this para-
24 graph to be conducted through a contract with
25 a qualified entity. In contracting for such serv-

1 ices, the Secretary shall competitively bid for an
2 outside vendor in accordance with the Federal
3 Acquisition Regulations. The Secretary shall
4 consult with retail community pharmacies dur-
5 ing the process of developing a request for pro-
6 posals, receiving and reviewing bids, and con-
7 tracting with such a vendor. Any contract en-
8 tered into as part of this bidding process shall
9 require the successful bidder to keep confiden-
10 tial and not disclose to any other Federal agen-
11 cy or other third parties, including State agen-
12 cies, all survey responses and any other disclo-
13 sure made by a retail community pharmacy
14 under this section.

15 “(G) AUDITING.—If the Secretary has rea-
16 sonable cause to believe that a survey response
17 submitted by a retail community pharmacy is
18 not complete or accurate, the Secretary may
19 conduct an audit of the records used by the re-
20 tail community pharmacy to develop that survey
21 response. In conducting such inspection the
22 Secretary may require a retail community phar-
23 macy to produce for inspection, consistent with
24 subparagraph (C), only the records actually re-
25 lied upon by the retail community pharmacy in

1 completing the survey. Retail community phar-
2 macies shall retain such records for one year,
3 and the Secretary shall not commence an in-
4 spection of records related to a survey response
5 more than one year after the survey response
6 was submitted by a retail community pharmacy.

7 “(H) PENALTY FOR FAILURE TO COOPER-
8 ATE IN AUDIT FOR PROVISION OF FALSE INFOR-
9 MATION.—The Secretary may impose a civil
10 monetary penalty on a retail community phar-
11 macy, if the pharmacy refuses a request by the
12 Secretary for information in connection with an
13 audit under subparagraph (G) or knowingly
14 provides false information in such an audit or
15 in a survey under this paragraph. The amount
16 of such penalty shall not exceed \$10,000 in the
17 case of such a refusal or \$10,000 for each item
18 of false information provided. The provisions of
19 section 1128A (other than subsections (a) and
20 (b)) shall apply to a civil money penalty under
21 this subparagraph in the same manner as such
22 provisions apply to a penalty or proceeding
23 under section 1128A(a).”.

1 **SEC. 3. ENCOURAGING GENERIC UTILIZATION AND OTHER**
2 **EVIDENCE-BASED COST CONTROL PRO-**
3 **GRAMS UNDER THE MEDICAID PROGRAM.**

4 Section 1927 of the Social Security Act (42 U.S.C.
5 1396r-8) is further amended by adding at the end the fol-
6 lowing new subsection:.

7 “(1) ESTABLISHMENT OF EVIDENCE-BASED PRE-
8 SCRIPTON DRUG PROGRAM.—

9 “(1) IN GENERAL.—In order to control costs
10 without reducing the quality of care when providing
11 payment for covered outpatient drugs. under the
12 State plan under this title, each State agency shall
13 establish and implement (beginning with the second
14 calendar quarter that begins after the date of the
15 enactment of this subsection), an evidence-based
16 prescription drug program in accordance with para-
17 graph (3). Each such program shall be designed in
18 a manner so as to result in a generic dispensing rate
19 for a fiscal year (or, in the case of implementation
20 after the beginning of a fiscal year for the remainder
21 of such fiscal year) that is at least the target generic
22 dispensing rate specified in paragraph (2) for the
23 State and fiscal year (or portion thereof) involved.
24 The Secretary is authorized to reduce the Federal fi-
25 nancial participation under this title for quarters in
26 the fiscal year with respect to covered outpatient

1 drugs to such amount as would reflect the State's
2 achievement of such a target generic dispensing rate
3 for such quarters and drugs.

4 “(2) TARGET GENERIC DISPENSING RATE.—
5 The target generic dispensing rate for a State for a
6 fiscal year (or portion thereof) is the lesser of—

7 “(A) 65 percent; or

8 “(B) in the case of—

9 “(i) a State with a generic dispensing
10 rate for the previous fiscal year that is
11 below the national average of such rate for
12 such fiscal year, 3 percentage points above
13 rate for the State in the previous fiscal
14 year; or

15 “(ii) any other State, at least 1 per-
16 cent point above such rate for the State in
17 the previous fiscal year.

18 “(3) REQUIREMENTS.—Each such program
19 shall—

20 “(A) prohibit reimbursement for covered
21 outpatient drugs that are determined to be inef-
22 fective by the Commissioner of Food and
23 Drugs;

24 “(B) adopt rules in order to ensure that
25 less expensive generic drugs will be used in as

1 many cases as possible with approval of the
2 physician;

3 “(C) consider the use of drugs with lower
4 abuse potential in substitution for drugs with
5 significant abuse potential; and

6 “(D) establish an independent pharmacy
7 and therapeutics committee to evaluate the ef-
8 fectiveness of covered outpatient drugs in the
9 development of such program.

10 “(4) GENERIC DISPENSING RATE.—For pur-
11 poses of this subsection, the term ‘generic dispensing
12 rate’ means, with respect to a multiple source drug,
13 the proportion of the total volume of such drugs dis-
14 pensed, that are generic drugs.”.

15 **SEC. 4. CHANGES TO DEFINITION OF MULTIPLE SOURCE**
16 **DRUG AND APPLICATION TO UPPER PAY-**
17 **MENT LIMITS.**

18 (a) IN GENERAL.—Section 1927 of the Social Secu-
19 rity Act (42 U.S.C. 1396r-8) is further amended—

20 (1) in subsection (e)(4)—

21 (A) by striking “each multiple source
22 drug” and inserting “each widely available mul-
23 tiple source drug”; and

24 (B) by striking “(or effective January 1,
25 2007, two or more)”; and

1 (2) in subsection (k)(7)(A)(i)—

2 (A) in the matter before subclause (I), by
3 striking “1 other drug product” and inserting
4 “2 other drug products”; and

5 (B) in each of subclauses (I), (II), and
6 (III), by striking “is” and inserting “are”.

7 (b) EFFECTIVE DATE.—The amendments made by
8 this section shall take effect on the first day of the second
9 calendar quarter beginning after the date of the enactment
10 of this Act.

11 **SEC. 5. GAO STUDY OF COMMUNITY PHARMACY DIS-**
12 **PENSING COSTS.**

13 (a) STUDY.—The Comptroller General of the United
14 States shall conduct a study on the costs of community
15 retail pharmacies to dispense prescription drugs.

16 (b) REPORT.—Not later than one year after the date
17 of the enactment of this Act, the Comptroller General shall
18 submit a report to Congress on the study conducted under
19 subsection (a).