

AMENDMENT NO. \_\_\_\_\_ Calendar No. \_\_\_\_\_

Purpose: To eliminate the coverage gap and require drug manufacturers to provide drug rebates for full-benefit dual eligibles under part D.

**IN THE SENATE OF THE UNITED STATES—111th Cong., 1st Sess.**

**H. R. 3590**

To amend the Internal Revenue Code of 1986 to modify the first-time homebuyers credit in the case of members of the Armed Forces and certain other Federal employees, and for other purposes.

Referred to the Committee on \_\_\_\_\_ and  
ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by Mr. NELSON of Florida to the amendment (No. 2786) proposed by Mr. REID

Viz:

1       On page 974, between lines 9 and 10, insert the fol-  
2       lowing:

3       (b) ELIMINATION OF COVERAGE GAP.—Section  
4       1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–  
5       102(b)) is further amended—

6               (1) in paragraph (3)(A), by striking “and (7)”  
7       and inserting “, (7), and (8)”;

1           (2) in paragraph (4)(B)(i), by inserting “sub-  
2           ject to paragraph (8)” after “purposes of this part”;  
3           and

4           (3) by adding at the end the following new  
5           paragraph:

6           “(8) PHASED-IN ELIMINATION OF COVERAGE  
7           GAP.—

8                   “(A) IN GENERAL.—For each year begin-  
9                   ning with 2011, the Secretary shall consistent  
10                   with this paragraph progressively increase the  
11                   initial coverage limit (described in subsection  
12                   (b)(3)) and decrease the annual out-of-pocket  
13                   threshold from the amounts otherwise computed  
14                   until there is a continuation of coverage from  
15                   the initial coverage limit for expenditures in-  
16                   curred through the total amount of expendi-  
17                   tures at which benefits are available under  
18                   paragraph (4).

19                   “(B) INCREASE IN INITIAL COVERAGE  
20                   LIMIT.—For a year beginning with 2011, the  
21                   initial coverage limit otherwise computed with-  
22                   out regard to this paragraph shall be increased  
23                   by  $\frac{1}{2}$  of the cumulative phase-in percentage (as  
24                   defined in subparagraph (D)(ii) for the year)

1 times the out-of-pocket gap amount (as defined  
2 in subparagraph (E)) for the year.

3 “(C) DECREASE IN ANNUAL OUT-OF-POCK-  
4 ET THRESHOLD.—For a year beginning with  
5 2011, the annual out-of-pocket threshold other-  
6 wise computed without regard to this paragraph  
7 shall be decreased by  $\frac{1}{2}$  of the cumulative  
8 phase-in percentage of the out-of-pocket gap  
9 amount for the year multiplied by 1.75.

10 “(D) PHASE-IN.—For purposes of this  
11 paragraph:

12 “(i) ANNUAL PHASE-IN PERCENT-  
13 AGE.—The term ‘annual phase-in percent-  
14 age’ means—

15 “(I) for 2011, 13 percent;

16 “(II) for 2012, 2013, 2014, and  
17 2015, 5 percent;

18 “(III) for 2016 through 2018,  
19 7.5 percent; and

20 “(IV) for 2019 and each subse-  
21 quent year, 10 percent.

22 “(ii) CUMULATIVE PHASE-IN PER-  
23 CENTAGE.—The term ‘cumulative phase-in  
24 percentage’ means for a year the sum of  
25 the annual phase-in percentage for the

1 year and the annual phase-in percentages  
2 for each previous year beginning with  
3 2011, but in no case more than 100 per-  
4 cent.

5 “(E) OUT-OF-POCKET GAP AMOUNT.—For  
6 purposes of this paragraph, the term ‘out-of-  
7 pocket gap amount’ means for a year the  
8 amount by which—

9 “(i) the annual out-of-pocket thresh-  
10 old specified in paragraph (4)(B) for the  
11 year (as determined as if this paragraph  
12 did not apply), exceeds

13 “(ii) the sum of—

14 “(I) the annual deductible under  
15 paragraph (1) for the year; and

16 “(II)  $\frac{1}{4}$  of the amount by which  
17 the initial coverage limit under para-  
18 graph (3) for the year (as determined  
19 as if this paragraph did not apply) ex-  
20 ceeds such annual deductible.”.

21 (c) REQUIRING DRUG MANUFACTURERS TO PROVIDE  
22 DRUG REBATES FOR FULL-BENEFIT DUAL ELIGIBLES.—

23 (1) IN GENERAL.—Section 1860D–2 of the So-  
24 cial Security Act (42 U.S.C. 1396r–8) is amended—

1 (A) in subsection (e)(1), in the matter be-  
2 fore subparagraph (A), by inserting “and sub-  
3 section (f)” after “this subsection”; and

4 (B) by adding at the end the following new  
5 subsection:

6 “(f) PRESCRIPTION DRUG REBATE AGREEMENT FOR  
7 FULL-BENEFIT DUAL ELIGIBLE INDIVIDUALS.—

8 “(1) IN GENERAL.—In this part, the term ‘cov-  
9 ered part D drug’ does not include any drug or bio-  
10 logic that is manufactured by a manufacturer that  
11 has not entered into and have in effect a rebate  
12 agreement described in paragraph (2).

13 “(2) REBATE AGREEMENT.—A rebate agree-  
14 ment under this subsection shall require the manu-  
15 facturer to provide to the Secretary a rebate for  
16 each rebate period (as defined in paragraph (6)(B))  
17 ending after December 31, 2010, in the amount  
18 specified in paragraph (3) for any covered part D  
19 drug of the manufacturer dispensed after December  
20 31, 2010, to any full-benefit dual eligible individual  
21 (as defined in paragraph (6)(A)) for which payment  
22 was made by a PDP sponsor under part D or a MA  
23 organization under part C for such period. Such re-  
24 bate shall be paid by the manufacturer to the Sec-  
25 retary not later than 30 days after the date of re-

1 receipt of the information described in section 1860D–  
2 12(b)(7), including as such section is applied under  
3 section 1857(f)(3).

4 “(3) REBATE FOR FULL-BENEFIT DUAL ELIGI-  
5 BLE MEDICARE DRUG PLAN ENROLLEES.—

6 “(A) IN GENERAL.—The amount of the re-  
7 bate specified under this paragraph for a manu-  
8 facturer for a rebate period, with respect to  
9 each dosage form and strength of any covered  
10 part D drug provided by such manufacturer  
11 and dispensed to a full-benefit dual eligible indi-  
12 vidual, shall be equal to the product of—

13 “(i) the total number of units of such  
14 dosage form and strength of the drug so  
15 provided and dispensed for which payment  
16 was made by a PDP sponsor under part D  
17 or a MA organization under part C for the  
18 rebate period (as reported under section  
19 1860D–12(b)(7), including as such section  
20 is applied under section 1857(f)(3)); and

21 “(ii) the amount (if any) by which—

22 “(I) the Medicaid rebate amount  
23 (as defined in subparagraph (B)) for  
24 such form, strength, and period, ex-  
25 ceeds

1                   “(II) the average Medicare drug  
2                   program full-benefit dual eligible re-  
3                   bate amount (as defined in subpara-  
4                   graph (C)) for such form, strength,  
5                   and period.

6                   “(B) MEDICAID REBATE AMOUNT.—For  
7                   purposes of this paragraph, the term ‘Medicaid  
8                   rebate amount’ means, with respect to each  
9                   dosage form and strength of a covered part D  
10                  drug provided by the manufacturer for a rebate  
11                  period—

12                  “(i) in the case of a single source  
13                  drug or an innovator multiple source drug,  
14                  the amount specified in paragraph  
15                  (1)(A)(ii) of section 1927(b) plus the  
16                  amount, if any, specified in paragraph  
17                  (2)(A)(ii) of such section, for such form,  
18                  strength, and period; or

19                  “(ii) in the case of any other covered  
20                  outpatient drug, the amount specified in  
21                  paragraph (3)(A)(i) of such section for  
22                  such form, strength, and period.

23                  “(C) AVERAGE MEDICARE DRUG PROGRAM  
24                  FULL-BENEFIT DUAL ELIGIBLE REBATE  
25                  AMOUNT.—For purposes of this subsection, the

1 term ‘average Medicare drug program full-ben-  
2 efit dual eligible rebate amount’ means, with re-  
3 spect to each dosage form and strength of a  
4 covered part D drug provided by a manufac-  
5 turer for a rebate period, the sum, for all PDP  
6 sponsors under part D and MA organizations  
7 administering a MA–PD plan under part C,  
8 of—

9 “(i) the product, for each such spon-  
10 sor or organization, of—

11 “(I) the sum of all rebates, dis-  
12 counts, or other price concessions (not  
13 taking into account any rebate pro-  
14 vided under paragraph (2) for such  
15 dosage form and strength of the drug  
16 dispensed, calculated on a per-unit  
17 basis, but only to the extent that any  
18 such rebate, discount, or other price  
19 concession applies equally to drugs  
20 dispensed to full-benefit dual eligible  
21 Medicare drug plan enrollees and  
22 drugs dispensed to PDP and MA–PD  
23 enrollees who are not full-benefit dual  
24 eligible individuals; and

1                   “(II) the number of the units of  
2                   such dosage and strength of the drug  
3                   dispensed during the rebate period to  
4                   full-benefit dual eligible individuals  
5                   enrolled in the prescription drug plans  
6                   administered by the PDP sponsor or  
7                   the MA–PD plans administered by the  
8                   MA–PD organization; divided by

9                   “(ii) the total number of units of such  
10                  dosage and strength of the drug dispensed  
11                  during the rebate period to full-benefit  
12                  dual eligible individuals enrolled in all pre-  
13                  scription drug plans administered by PDP  
14                  sponsors and all MA–PD plans adminis-  
15                  tered by MA–PD organizations.

16                  “(4) LENGTH OF AGREEMENT.—The provisions  
17                  of paragraph (4) of section 1927(b) (other than  
18                  clauses (iv) and (v) of subparagraph (B)) shall apply  
19                  to rebate agreements under this subsection in the  
20                  same manner as such paragraph applies to a rebate  
21                  agreement under such section.

22                  “(5) OTHER TERMS AND CONDITIONS.—The  
23                  Secretary shall establish other terms and conditions  
24                  of the rebate agreement under this subsection, in-

1 including terms and conditions related to compliance,  
2 that are consistent with this subsection.

3 “(6) DEFINITIONS.—In this subsection and sec-  
4 tion 1860D–12(b)(7):

5 “(A) FULL-BENEFIT DUAL ELIGIBLE INDI-  
6 VIDUAL.—The term ‘full-benefit dual eligible in-  
7 dividual’ has the meaning given such term in  
8 section 1935(e)(6).

9 “(B) REBATE PERIOD.—The term ‘rebate  
10 period’ has the meaning given such term in sec-  
11 tion 1927(k)(8).”.

12 (2) REPORTING REQUIREMENT FOR THE DE-  
13 TERMINATION AND PAYMENT OF REBATES BY MANU-  
14 FACTURES RELATED TO REBATE FOR FULL-BENEFIT  
15 DUAL ELIGIBLE MEDICARE DRUG PLAN ENROLL-  
16 EES.—

17 (A) REQUIREMENTS FOR PDP SPON-  
18 SORS.—Section 1860D–12(b) of the Social Se-  
19 curity Act (42 U.S.C. 1395w–112(b)) is amend-  
20 ed by adding at the end the following new para-  
21 graph:

22 “(7) REPORTING REQUIREMENT FOR THE DE-  
23 TERMINATION AND PAYMENT OF REBATES BY MANU-  
24 FACTURERS RELATED TO REBATE FOR FULL-BEN-

1 EFIT DUAL ELIGIBLE MEDICARE DRUG PLAN EN-  
2 ROLLEES.—

3 “(A) IN GENERAL.—For purposes of the  
4 rebate under section 1860D–2(f) for contract  
5 years beginning on or after January 1, 2011,  
6 each contract entered into with a PDP sponsor  
7 under this part with respect to a prescription  
8 drug plan shall require that the sponsor comply  
9 with subparagraphs (B) and (C).

10 “(B) REPORT FORM AND CONTENTS.—Not  
11 later than 60 days after the end of each rebate  
12 period (as defined in section 1860D–2(f)(6)(B))  
13 within such a contract year to which such sec-  
14 tion applies, a PDP sponsor of a prescription  
15 drug plan under this part shall report to each  
16 manufacturer—

17 “(i) information (by National Drug  
18 Code number) on the total number of units  
19 of each dosage, form, and strength of each  
20 drug of such manufacturer dispensed to  
21 full-benefit dual eligible Medicare drug  
22 plan enrollees under any prescription drug  
23 plan operated by the PDP sponsor during  
24 the rebate period;

1           “(ii) information on the price dis-  
2           counts, price concessions, and rebates for  
3           such drugs for such form, strength, and  
4           period;

5           “(iii) information on the extent to  
6           which such price discounts, price conces-  
7           sions, and rebates apply equally to full-  
8           benefit dual eligible Medicare drug plan  
9           enrollees and PDP enrollees who are not  
10          full-benefit dual eligible Medicare drug  
11          plan enrollees; and

12          “(iv) any additional information that  
13          the Secretary determines is necessary to  
14          enable the Secretary to calculate the aver-  
15          age Medicare drug program full-benefit  
16          dual eligible rebate amount (as defined in  
17          paragraph (3)(C) of such section), and to  
18          determine the amount of the rebate re-  
19          quired under this section, for such form,  
20          strength, and period.

21          Such report shall be in a form consistent with  
22          a standard reporting format established by the  
23          Secretary.

24          “(C) SUBMISSION TO SECRETARY.—Each  
25          PDP sponsor shall promptly transmit a copy of

1 the information reported under subparagraph  
2 (B) to the Secretary for the purpose of audit  
3 oversight and evaluation.

4 “(D) CONFIDENTIALITY OF INFORMA-  
5 TION.—The provisions of subparagraph (D) of  
6 section 1927(b)(3), relating to confidentiality of  
7 information, shall apply to information reported  
8 by PDP sponsors under this paragraph in the  
9 same manner that such provisions apply to in-  
10 formation disclosed by manufacturers or whole-  
11 salers under such section, except—

12 “(i) that any reference to ‘this sec-  
13 tion’ in clause (i) of such subparagraph  
14 shall be treated as being a reference to this  
15 section;

16 “(ii) the reference to the Director of  
17 the Congressional Budget Office in clause  
18 (iii) of such subparagraph shall be treated  
19 as including a reference to the Medicare  
20 Payment Advisory Commission; and

21 “(iii) clause (iv) of such subparagraph  
22 shall not apply.

23 “(E) OVERSIGHT.—Information reported  
24 under this paragraph may be used by the In-  
25 spector General of the Department of Health

1 and Human Services for the statutorily author-  
2 ized purposes of audit, investigation, and eval-  
3 uations.

4 “(F) PENALTIES FOR FAILURE TO PRO-  
5 VIDE TIMELY INFORMATION AND PROVISION OF  
6 FALSE INFORMATION.—In the case of a PDP  
7 sponsor—

8 “(i) that fails to provide information  
9 required under subparagraph (B) on a  
10 timely basis, the sponsor is subject to a  
11 civil money penalty in the amount of  
12 \$10,000 for each day in which such infor-  
13 mation has not been provided; or

14 “(ii) that knowingly (as defined in  
15 section 1128A(i)) provides false informa-  
16 tion under such subparagraph, the sponsor  
17 is subject to a civil money penalty in an  
18 amount not to exceed \$100,000 for each  
19 item of false information.

20 Such civil money penalties are in addition to  
21 other penalties as may be prescribed by law.  
22 The provisions of section 1128A (other than  
23 subsections (a) and (b)) shall apply to a civil  
24 money penalty under this subparagraph in the

1 same manner as such provisions apply to a pen-  
2 alty or proceeding under section 1128A(a).”.

3 (B) APPLICATION TO MA ORGANIZA-  
4 TIONS.—Section 1857(f)(3) of the Social Secu-  
5 rity Act (42 U.S.C. 1395w–27(f)(3)) is amend-  
6 ed by adding at the end the following:

7 “(D) REPORTING REQUIREMENT RELATED  
8 TO REBATE FOR FULL-BENEFIT DUAL ELIGIBLE  
9 MEDICARE DRUG PLAN ENROLLEES.—Section  
10 1860D–12(b)(7).”.

11 (3) DEPOSIT OF REBATES INTO MEDICARE PRE-  
12 SCRIPTON DRUG ACCOUNT.—Section 1860D–16(c)  
13 of such Act (42 U.S.C. 1395w–116(c)) is amended  
14 by adding at the end the following new paragraph:

15 “(6) REBATE FOR FULL-BENEFIT DUAL ELIGI-  
16 BLE MEDICARE DRUG PLAN ENROLLEES.—Amounts  
17 paid under a rebate agreement under section  
18 1860D–2(f) shall be deposited into the Account and  
19 shall be used to pay for all or part of the gradual  
20 elimination of the coverage gap under section  
21 1860D–2(b)(7).”.

22 (d) SUNSET OF MEDICARE COVERAGE GAP DIS-  
23 COUNT PROGRAM.—Section 3301 of this Act is amended  
24 by adding at the end the following new subsection:

1       “(e) SUNSET OF MEDICARE COVERAGE GAP DIS-  
2 COUNT PROGRAM.—The amendments made by this section  
3 shall cease to be effective as of the date on which there  
4 is a continuation of coverage from the initial coverage limit  
5 for expenditures incurred through the total amount of ex-  
6 penditures at which benefits are available under section  
7 1860D–2(b)(4).”.