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(Original Signature of Member)

110TH CONGRESS  
1ST SESSION

# H. R.

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To amend title XVIII of the Social Security Act to deliver a meaningful benefit and lower prescription drug prices under the Medicare Program.

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## IN THE HOUSE OF REPRESENTATIVES

Mr. BERRY introduced the following bill; which was referred to the Committee  
on \_\_\_\_\_

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# A BILL

To amend title XVIII of the Social Security Act to deliver a meaningful benefit and lower prescription drug prices under the Medicare Program.

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 “Medicare Prescription  
5 Drug Savings and Choice Act of 2007”.

1 **SEC. 2. ESTABLISHMENT OF MEDICARE OPERATED PRE-**  
2 **SCRIPTION DRUG PLAN OPTION.**

3 (a) IN GENERAL.—Subpart 2 of part D of the Social  
4 Security Act is amended by inserting after section 1860D–  
5 11 (42 U.S.C. 1395w–111) the following new section:

6 “MEDICARE OPERATED PRESCRIPTION DRUG PLAN  
7 OPTION

8 “SEC. 1860D–11A. (a) IN GENERAL.—Notwith-  
9 standing any other provision of this part, for each year  
10 (beginning with 2009), in addition to any plans offered  
11 under section 1860D–11, the Secretary shall offer one or  
12 more medicare operated prescription drug plans (as de-  
13 fined in subsection (c)) with a service area that consists  
14 of the entire United States and shall enter into negotia-  
15 tions in accordance with subsection (b) with pharma-  
16 ceutical manufacturers to reduce the purchase cost of cov-  
17 ered part D drugs for eligible part D individuals who en-  
18 roll in such a plan.

19 “(b) NEGOTIATIONS.—Notwithstanding section  
20 1860D–11(i), for purposes of offering a medicare operated  
21 prescription drug plan under this section, the Secretary  
22 shall negotiate with pharmaceutical manufacturers with  
23 respect to the purchase price of covered part D drugs in  
24 a Medicare operated prescription drug plan and shall en-  
25 courage the use of more affordable therapeutic equivalents  
26 to the extent such practices do not override medical neces-

1 sity as determined by the prescribing physician. To the  
2 extent practicable and consistent with the previous sen-  
3 tence, the Secretary shall implement strategies similar to  
4 those used by other Federal purchasers of prescription  
5 drugs, and other strategies, including the use of a for-  
6 mulary and formulary incentives in subsection (e), to re-  
7 duce the purchase cost of covered part D drugs.

8 “(c) MEDICARE OPERATED PRESCRIPTION DRUG  
9 PLAN DEFINED.—For purposes of this part, the term  
10 ‘medicare operated prescription drug plan’ means a pre-  
11 scription drug plan that offers qualified prescription drug  
12 coverage and access to negotiated prices described in sec-  
13 tion 1860D–2(a)(1)(A). Such a plan may offer supple-  
14 mental prescription drug coverage in the same manner as  
15 other qualified prescription drug coverage offered by other  
16 prescription drug plans.

17 “(d) MONTHLY BENEFICIARY PREMIUM.—

18 “(1) QUALIFIED PRESCRIPTION DRUG COV-  
19 ERAGE.—The monthly beneficiary premium for  
20 qualified prescription drug coverage and access to  
21 negotiated prices described in section 1860D–  
22 2(a)(1)(A) to be charged under a medicare operated  
23 prescription drug plan shall be uniform nationally.  
24 Such premium for months in 2009 and each suc-  
25 ceeding year shall be based on the average monthly

1 per capita actuarial cost of offering the medicare op-  
2 erated prescription drug plan for the year involved,  
3 including administrative expenses.

4 “(2) SUPPLEMENTAL PRESCRIPTION DRUG COV-  
5 ERAGE.—Insofar as a medicare operated prescrip-  
6 tion drug plan offers supplemental prescription drug  
7 coverage, the Secretary may adjust the amount of  
8 the premium charged under paragraph (1).

9 “(e) USE OF A FORMULARY AND FORMULARY INCEN-  
10 TIVES.—

11 “(1) IN GENERAL.—With respect to the oper-  
12 ation of a medicare operated prescription drug plan,  
13 the Secretary shall establish and apply a formulary  
14 (and may include formulary incentives described in  
15 paragraph (2)(C)(ii)) in accordance with this sub-  
16 section in order to—

17 “(A) increase patient safety;

18 “(B) increase appropriate use and reduce  
19 inappropriate use of drugs; and

20 “(C) reward value.

21 “(2) DEVELOPMENT OF INITIAL FORMULARY.—

22 “(A) IN GENERAL.—In selecting covered  
23 part D drugs for inclusion in a formulary. the  
24 Secretary shall consider clinical benefit and  
25 price.

1           “(B) ROLE OF AHRQ.—The Director of the  
2           Agency for Healthcare Research and Quality  
3           shall be responsible for assessing the clinical  
4           benefit of covered part D drugs and making  
5           recommendations to the Secretary regarding  
6           which drugs should be included in the for-  
7           mulary. In conducting such assessments and  
8           making such recommendations, the Director  
9           shall—

10                   “(i) consider safety concerns including  
11                   those identified by the Federal Food and  
12                   Drug Administration;

13                   “(ii) use available data and evalua-  
14                   tions, with priority given to randomized  
15                   controlled trials, to examine clinical effec-  
16                   tiveness, comparative effectiveness, safety,  
17                   and enhanced compliance with a drug regi-  
18                   men;

19                   “(iii) use the same classes of drugs  
20                   developed by United States Pharmacopeia  
21                   for this part;

22                   “(iv) consider evaluations made by—  
23                           “(I) the Director under section  
24                           1013 of Medicare Prescription Drug,

1 Improvement, and Modernization Act  
2 of 2003;

3 “(II) other Federal entities, such  
4 as the Secretary of Veterans Affairs;  
5 and

6 “(III) other private and public  
7 entities, such as the Drug Effective-  
8 ness Review Project and Medicaid  
9 programs; and

10 “(v) recommend to the Secretary—

11 “(I) those drugs in a class that  
12 provide a greater clinical benefit, in-  
13 cluding fewer safety concerns or less  
14 risk of side-effects, than another drug  
15 in the same class that should be in-  
16 cluded in the formulary;

17 “(II) those drugs in a class that  
18 provide less clinical benefit, including  
19 greater safety concerns or a greater  
20 risk of side-effects, than another drug  
21 in the same class that should be ex-  
22 cluded from the formulary; and

23 “(III) drugs in a class with same  
24 or similar clinical benefit for which it  
25 would be appropriate for the Sec-

1                   retary to competitively bid (or nego-  
2                   tiate) for placement on the formulary.

3                   “(C) CONSIDERATION OF AHRQ REC-  
4                   COMMENDATIONS.—

5                   “(i) IN GENERAL.—The Secretary,  
6                   after taking into consideration the rec-  
7                   ommendations under subparagraph (B)(v),  
8                   shall establish a formulary, and formulary  
9                   incentives, to encourage use of covered  
10                  part D drugs that—

11                  “(I) have a lower cost and pro-  
12                  vide a greater clinical benefit than  
13                  other drugs;

14                  “(II) have a lower cost than  
15                  other drugs with same or similar clin-  
16                  ical benefit; and

17                  “(III) drugs that have the same  
18                  cost but provide greater clinical ben-  
19                  efit than other drugs.

20                  “(ii) FORMULARY INCENTIVES.—The  
21                  formulary incentives under clause (i) may  
22                  be in the form of one or more of the fol-  
23                  lowing:

24                  “(I) Tiered copayments.

25                  “(II) Reference pricing.

1 “(III) Prior authorization.

2 “(IV) Step therapy.

3 “(V) Medication therapy manage-  
4 ment.

5 “(VI) Generic drug substitution.

6 “(iii) FLEXIBILITY.—In applying such  
7 formulary incentives the Secretary may de-  
8 cide not to impose any cost-sharing for a  
9 covered part D drug for which—

10 “(I) the elimination of cost shar-  
11 ing would be expected to increase  
12 compliance with a drug regimen; and

13 “(II) compliance would be ex-  
14 pected to produce savings under part  
15 A or B or both.

16 “(3) LIMITATIONS ON FORMULARY.—In any  
17 formulary established under this subsection, the for-  
18 mulary may not be changed during a year, except—

19 “(A) to add a generic version of a covered  
20 part D drug that entered the market;

21 “(B) to remove such a drug for which a  
22 safety problem is found; and

23 “(C) to add a drug that the Secretary  
24 identifies as a drug which treats a condition for  
25 which there has not previously been a treatment

1 option or for which a clear and significant ben-  
2 efit has been demonstrated over other covered  
3 part D drugs.

4 “(4) ADDING DRUGS TO THE INITIAL FOR-  
5 MULARY.—

6 “(A) USE OF ADVISORY COMMITTEE.—The  
7 Secretary shall establish and appoint an advi-  
8 sory committee (in this paragraph referred to  
9 as the ‘advisory committee’)—

10 “(i) to review petitions from drug  
11 manufacturers, health care provider orga-  
12 nizations, patient groups, and other enti-  
13 ties for inclusion of a drug in, or other  
14 changes to, such formulary; and

15 “(ii) to recommend any changes to the  
16 formulary established under this sub-  
17 section.

18 “(B) COMPOSITION.—The advisory com-  
19 mittee shall be composed of 9 members and  
20 shall include representatives of physicians,  
21 pharmacists, and consumers and others with ex-  
22 pertise in evaluating prescription drugs. The  
23 Secretary shall select members based on their  
24 knowledge of pharmaceuticals and the Medicare  
25 population. Members shall be deemed to be spe-

1           cial Government employees for purposes of ap-  
2           plying the conflict of interest provisions under  
3           section 208 of title 18, United States Code, and  
4           no waiver of such provisions for such a member  
5           shall be permitted.

6           “(C) CONSULTATION.—The advisory com-  
7           mittee shall consult, as necessary, with physi-  
8           cians who are specialists in treating the disease  
9           for which a drug is being considered.

10          “(D) REQUEST FOR STUDIES.—The advi-  
11          sory committee may request the Agency for  
12          Healthcare Research and Quality or an aca-  
13          demic or research institution to study and make  
14          a report on a petition described in subpara-  
15          graph (A)(ii) in order to assess—

16                   “(i) clinical effectiveness;

17                   “(ii) comparative effectiveness;

18                   “(iii) safety; and

19                   “(iv) enhanced compliance with a  
20          drug regimen.

21          “(E) RECOMMENDATIONS.—The advisory  
22          committee shall make recommendations to the  
23          Secretary regarding—

24                   “(i) whether a covered part D drug is  
25          found to provide a greater clinical benefit,

1 including fewer safety concerns or less risk  
2 of side-effects, than another drug in the  
3 same class that is currently included in the  
4 formulary and should be included in the  
5 formulary;

6 “(ii) whether a covered part D drug is  
7 found to provide less clinical benefit, in-  
8 cluding greater safety concerns or a great-  
9 er risk of side-effects, than another drug in  
10 the same class that is currently included in  
11 the formulary and should not be included  
12 in the formulary; and

13 “(iii) whether a covered part D drug  
14 has the same or similar clinical benefit to  
15 a drug in the same class that is currently  
16 included in the formulary and whether the  
17 drug should be included in the formulary.

18 “(F) LIMITATIONS ON REVIEW OF MANU-  
19 FACTURER PETITIONS.—The advisory com-  
20 mittee shall not review a petition of a drug  
21 manufacturer under subparagraph (A)(ii) with  
22 respect to a covered part D drug unless the pe-  
23 tition is accompanied by the following:

24 “(i) Raw data from clinical trials on  
25 the safety and effectiveness of the drug.

1                   “(ii) Any data from clinical trials con-  
2                   ducted using active controls on the drug or  
3                   drugs that are the current standard of  
4                   care.

5                   “(iii) Any available data on compara-  
6                   tive effectiveness of the drug.

7                   “(iv) Any other information the Sec-  
8                   retary requires for the advisory committee  
9                   to complete its review.

10                  “(G) RESPONSE TO RECOMMENDATIONS.—  
11                  The Secretary shall review the recommenda-  
12                  tions of the advisory committee and if the Sec-  
13                  retary accepts such recommendations the Sec-  
14                  retary shall modify the formulary established  
15                  under this subsection accordingly. Nothing in  
16                  this section shall preclude the Secretary from  
17                  adding to the formulary a drug for which the  
18                  Director of the Agency for Healthcare Research  
19                  and Quality or the advisory committee has not  
20                  made a recommendation.

21                  “(H) NOTICE OF CHANGES.—The Sec-  
22                  retary shall provide timely notice to bene-  
23                  ficiaries and health professionals about changes  
24                  to the formulary or formulary incentives.

1           “(f) INFORMING BENEFICIARIES.—The Secretary  
2 shall take steps to inform beneficiaries about the avail-  
3 ability of a Medicare operated drug plan or plans including  
4 providing information in the annual handbook distributed  
5 to all beneficiaries and adding information to the official  
6 public Medicare website related to prescription drug cov-  
7 erage available through this part.

8           “(g) APPLICATION OF ALL OTHER REQUIREMENTS  
9 FOR PRESCRIPTION DRUG PLANS.—Except as specifically  
10 provided in this section, any Medicare operated drug plan  
11 shall meet the same requirements as apply to any other  
12 prescription drug plan, including the requirements of sec-  
13 tion 1860D-4(b)(1) relating to assuring pharmacy ac-  
14 cess).”.

15           (b) CONFORMING AMENDMENTS.—

16           (1) Section 1860D-3(a) of the Social Security  
17 Act (42 U.S.C. 1395w-103(a)) is amended by add-  
18 ing at the end the following new paragraph:

19           “(4) AVAILABILITY OF THE MEDICARE OPER-  
20 ATED PRESCRIPTION DRUG PLAN.—A medicare oper-  
21 ated prescription drug plan (as defined in section  
22 1860D-11A(c)) shall be offered nationally in accord-  
23 ance with section 1860D-11A.”.

1           (2)(A) Section 1860D–3 of the Social Security  
2 Act (42 U.S.C. 1395w-103) is amended by adding at  
3 the end the following new subsection:

4           “(c) PROVISIONS ONLY APPLICABLE IN 2006, 2007,  
5 AND 2008.—The provisions of this section shall only apply  
6 with respect to 2006, 2007, and 2008.”.

7           (B) Section 1860D–11(g) of such Act (42  
8 U.S.C. 1395w-111(g)) is amended by adding at the  
9 end the following new paragraph:

10           “(8) NO AUTHORITY FOR FALLBACK PLANS  
11 AFTER 2008.—A fallback prescription drug plan shall  
12 not be available after December 31, 2008.”.

13           (3) Section 1860D–13(c)(3) of such Act (42  
14 U.S.C. 1395w–113(c)(3)) is amended—

15           (A) in the heading, by inserting “AND  
16 MEDICARE OPERATED PRESCRIPTION DRUG  
17 PLANS” after “FALLBACK PLANS”; and

18           (B) by inserting “or a medicare operated  
19 prescription drug plan” after “a fallback pre-  
20 scription drug plan”.

21           (4) Section 1860D–16(b)(1) of such Act (42  
22 U.S.C.1395w–116(b)(1)) is amended—

23           (A) in subparagraph (C), by striking  
24 “and” after the semicolon at the end;

1 (B) in subparagraph (D), by striking the  
2 period at the end and inserting “; and”; and

3 (C) by adding at the end the following new  
4 subparagraph:

5 “(E) payments for expenses incurred with  
6 respect to the operation of medicare operated  
7 prescription drug plans under section 1860D–  
8 11A.”.

9 (5) Section 1860D–41(a) of such Act (42  
10 U.S.C. 1395w–151(a)) is amended by adding at the  
11 end the following new paragraph:

12 “(19) MEDICARE OPERATED PRESCRIPTION  
13 DRUG PLAN.—The term ‘medicare operated prescrip-  
14 tion drug plan’ has the meaning given such term in  
15 section 1860D–11A(c).”.

16 (c) EFFECTIVE DATE.—The amendments made by  
17 this section shall take effect as if included in the enact-  
18 ment of section 101 of the Medicare Prescription Drug,  
19 Improvement, and Modernization Act of 2003.

20 **SEC. 3. IMPROVED APPEALS PROCESS UNDER THE MEDI-**  
21 **CARE OPERATED PRESCRIPTION DRUG PLAN.**

22 Section 1860D–4(h) of the Social Security Act (42  
23 U.S.C. 1305w-104(h)) is amended by adding at the end  
24 the following new paragraph:

1       “(h) APPEALS PROCESS FOR MEDICARE OPERATED  
2 PRESCRIPTION DRUG PLAN.—

3           “(1) IN GENERAL.—The Secretary shall develop  
4 a well-defined process for appeals for denials of ben-  
5 efits under this part under the medicare operated  
6 prescription drug plan. Such process shall be effi-  
7 cient, impose minimal administrative burdens, and  
8 ensure the timely procurement of non-formulary  
9 drugs or exemption from formulary incentives when  
10 medically necessary. Medical necessity shall be based  
11 on professional medical judgment, the medical condi-  
12 tion of the beneficiary, and other medical evidence.  
13 Such appeals process shall include—

14           “(A) an initial review and determination  
15 made by the Secretary; and

16           “(B) for appeals denied during the initial  
17 review and determination, the option of an ex-  
18 ternal review and determination by an inde-  
19 pendent entity selected by the Secretary.

20           “(2) CONSULTATION IN DEVELOPMENT OF  
21 PROCESS.—In developing the appeals process under  
22 paragraph (1), the Secretary shall consult with con-  
23 sumer and patient groups, as well as other key  
24 stakeholders to ensure the goals described in para-  
25 graph (1) are achieved.”.

1 **SEC. 4. PHARMACY PAYMENT UNDER THE MEDICARE OP-**  
2 **ERATED PRESCRIPTION DRUG PLAN.**

3 Section 1860D–12(b) of the Social Security Act (42  
4 U.S.C. 1395w–112 (b)) is amended by adding at the end  
5 the following new paragraph:

6 “(4) PHARMACY PAYMENT UNDER THE MEDI-  
7 CARE OPERATED PRESCRIPTION DRUG PLAN.—

8 “(A) IN GENERAL.—Under the medicare  
9 operated prescription drug plan, the Secretary  
10 shall develop a system for payment to phar-  
11 macies. Such a system shall include a require-  
12 ment that the plan shall issue, mail, or other-  
13 wise transmit payment for all clean claims sub-  
14 mitted under this part within the applicable  
15 number of calendar days after the date on  
16 which the claim is received.

17 “(B) DEFINITIONS.—In this paragraph:

18 “(i) CLEAN CLAIM.—The term ‘clean  
19 claim’ means a claim, with respect to a  
20 covered part D drug, that has no apparent  
21 defect or impropriety (including any lack  
22 of any required substantiating documenta-  
23 tion) or particular circumstance requiring  
24 special treatment that prevents timely pay-  
25 ment from being made on the claim under  
26 this part.

1 “(ii) APPLICABLE NUMBER OF CAL-  
2 ENDAR DAYS.—The term ‘applicable num-  
3 ber of calendar days’ means—

4 “(I) with respect to claims sub-  
5 mitted electronically, 14 calendar  
6 days; and

7 “(II) with respect to claims sub-  
8 mitted otherwise, 30 calendar days.

9 “(C) PROCEDURES INVOLVING CLAIMS.—

10 “(i) CLAIMS DEEMED TO BE CLEAN  
11 CLAIMS.—

12 “(I) IN GENERAL.—A claim for a  
13 covered part D drug shall be deemed  
14 to be a clean claim for purposes of  
15 this paragraph if the Secretary does  
16 not provide a notification of deficiency  
17 to the claimant by the 10th day that  
18 begins after the date on which the  
19 claim is submitted.

20 “(II) NOTIFICATION OF DEFICI-  
21 CIENCY.—For purposes of subclause  
22 (I), the term ‘notification of defi-  
23 ciency’ means a notification that  
24 specifies all defects or improprieties in  
25 the claim involved and that lists all

1 additional information or documents  
2 necessary for the proper processing  
3 and payment of the claim.

4 “(ii) PAYMENT OF CLEAN PORTIONS  
5 OF CLAIMS.—The Secretary shall, as ap-  
6 propriate, pay any portion of a claim for a  
7 covered part D drug under the medicare  
8 operated prescription drug plan that would  
9 be a clean claim but for a defect or impro-  
10 priety in a separate portion of the claim in  
11 accordance with subparagraph (A).

12 “(iii) OBLIGATION TO PAY.—A claim  
13 for a covered part D drug submitted to the  
14 Secretary that is not paid or contested by  
15 the provider within the applicable number  
16 of calendar days (as defined in subpara-  
17 graph (B)) shall be deemed to be a clean  
18 claim and shall be paid by the Secretary in  
19 accordance with subparagraph (A).

20 “(iv) DATE OF PAYMENT OF CLAIM.—  
21 Payment of a clean claim under subpara-  
22 graph (A) is considered to have been made  
23 on the date on which full payment is re-  
24 ceived by the provider.

1                   “(D)   ELECTRONIC   TRANSFER   OF  
2                   FUNDS.—The Secretary shall pay all clean  
3                   claims submitted electronically by an electronic  
4                   funds transfer mechanism.”.