

107TH CONGRESS  
1ST SESSION

# H. R. 3317

To amend title XVIII of the Social Security Act to provide for coverage under the Medicare Program of self-administered drugs that, when used as a replacement for covered drugs, result in overall cost savings to the program.

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## IN THE HOUSE OF REPRESENTATIVES

NOVEMBER 16, 2001

Ms. BALDWIN (for herself, Ms. WOOLSEY, Mr. KLECZKA, Mr. BARRETT of Wisconsin, Mr. MATSUI, Mr. FRANK, Mrs. MINK of Hawaii, Ms. LEE, Ms. KILPATRICK, Ms. SCHAKOWSKY, Mr. HILLIARD, Mr. EVANS, Mrs. MCCARTHY of New York, and Mr. ALLEN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To amend title XVIII of the Social Security Act to provide for coverage under the Medicare Program of self-administered drugs that, when used as a replacement for covered drugs, result in overall cost savings to the 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 Drug Cost  
5 Savings Act of 2001”.

1 **SEC. 2. MEDICARE COVERAGE OF COST SAVING SELF-AD-**  
2 **MINISTERED DRUGS USED AS A REPLACE-**  
3 **MENT FOR COVERED DRUGS.**

4 (a) COVERAGE.—Section 1861(s)(2) of the Social Se-  
5 curity Act (42 U.S.C. 1395x(s)(2)), as amended by sec-  
6 tions 102(a) and 105(a) of the Medicare, Medicaid, and  
7 SCHIP Benefits Improvement and Protection Act of 2000  
8 (114 Stat. 2763A–468, 471), as enacted into law by sec-  
9 tion 1(a)(6) of Public Law 106–554, is amended—

10 (1) by striking “and” at the end of subpara-  
11 graph (U);

12 (2) by striking the period at the end of sub-  
13 paragraph (V) and inserting “; and”; and

14 (3) by inserting after subparagraph (V) the fol-  
15 lowing new subparagraph:

16 “(W) a self-administered drug (which is ap-  
17 proved by the Food and Drug Administration)  
18 that—

19 “(i) is a full replacement for a drug or  
20 drug therapy which is otherwise covered under  
21 this title; and

22 “(ii) as a full replacement for such drug or  
23 drug therapy, results in overall cost savings  
24 under this title for the treatment of the condi-  
25 tion for which such drug or drug therapy is pre-  
26 scribed (as determined by the Secretary);”.

1       (b) PROHIBITION ON MANDATED SUBSTITUTION FOR  
2 INTRAVENOUS DRUGS.—A carrier (under section 1842 of  
3 the Social Security Act (42 U.S.C. 1395u)), or fiscal inter-  
4 mediary (under section 1816 of such Act (42 U.S.C.  
5 1395h)), may not require the substitution of a self-admin-  
6 istered drug (under section 1861(s)(2)(W) of the Social  
7 Security Act, as added by subsection (a)) for an intra-  
8 venously-administered drug or drug therapy if, in the  
9 judgment of the physician of the individual diagnosed with  
10 a condition for which the drug or drug therapy has been  
11 prescribed, intravenous-administration of the drug or drug  
12 therapy is more appropriate or effective to treat the indi-  
13 vidual's condition.

14       (c) GAO STUDY.—

15           (1) IN GENERAL.—The Comptroller General of  
16 the United States shall conduct a study on the im-  
17 plementation by the Secretary of Health and Human  
18 Services of section 1861(s)(2)(W) of the Social Se-  
19 curity Act, as added by subsection (a). Such study  
20 shall include the identification or evaluation of the  
21 following:

22           (A) The self-administered drugs that the  
23 Secretary has determined are appropriate for  
24 use as replacement drugs under that section.

1           (B) The replacement self-administered  
2           drugs for which the Secretary has made pay-  
3           ment under the medicare program under title  
4           XVIII of the Social Security Act (42 U.S.C.  
5           1395 et seq.).

6           (C) The amount of savings attributable to  
7           the use of such replacement self-administered  
8           drugs.

9           (D) Additional self-administered drugs  
10          that the Comptroller General determines would  
11          be appropriate for use under that section.

12          (E) Any impact on utilization and bene-  
13          ficiary access to self-administered drugs under  
14          the medicare program.

15          (2) REPORT TO CONGRESS.—Not later than one  
16          year after the date of the enactment of this Act, the  
17          Comptroller General shall submit to Congress a re-  
18          port on the study conducted under paragraph (1),  
19          and may include such recommendations as the  
20          Comptroller General determines appropriate.

21          (d) EFFECTIVE DATE.—The amendments made by  
22          subsection (a) apply to drugs furnished on or after the  
23          date that is 90 days after the date of the enactment of  
24          this Act.

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