I

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.

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

---

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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Medicare Drug Cost Savings Act of 2001''.

SEC. 2. MEDICARE COVERAGE OF COST SAVING SELF-ADMINISTERED DRUGS USED AS A REPLACEMENT FOR COVERED DRUGS.

(a) COVERAGE.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)), as amended by sections 102(a) and 105(a) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (114 Stat. 2763A–468, 471), as enacted into law by section 1(a)(6) of Public Law 106–554, is amended—

(1) by striking ''and'' at the end of subparagraph (U);

(2) by striking the period at the end of subparagraph (V) and inserting ''; and''; and

(3) by inserting after subparagraph (V) the following new subparagraph:

''(W) a self-administered drug (which is approved by the Food and Drug Administration) that—

''(i) is a full replacement for a drug or drug therapy which is otherwise covered under this title; and

''(ii) as a full replacement for such drug or drug therapy, results in overall cost savings under this title for the treatment of the condition for which such drug or drug therapy is prescribed (as determined by the Secretary);''.

(b) PROHIBITION ON MANDATED SUBSTITUTION FOR INTRAVENOUS DRUGS.—A carrier (under section 1842 of the Social Security Act (42 U.S.C. 1395u)), or fiscal intermediary (under section 1816 of such Act (42 U.S.C. 1395h)), may not require the substitution of a self-administered drug (under section 1861(s)(2)(W) of the Social Security Act, as added by subsection (a)) for an intravenously-administered drug or drug therapy if, in the judgment of the physician of the individual diagnosed with a condition for which the drug or drug therapy has been prescribed, intravenous-administration of the drug or drug therapy is more appropriate or effective to treat the individual's condition.

(c) GAO STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study on the implementation by the Secretary of Health and Human Services of section 1861(s)(2)(W) of the Social Security Act, as added by subsection (a). Such study shall include the identification or evaluation of the following:

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

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

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

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

(E) Any impact on utilization and beneficiary access to self-administered drugs under the medicare program.

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

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

○