

107TH CONGRESS
1ST SESSION

H. R. 1758

To amend title XVIII of the Social Security Act to provide for coverage under part B of the Medicare Program of certain beta interferons and other biologicals and drugs approved by the Food and Drug Administration for treatment of multiple sclerosis.

IN THE HOUSE OF REPRESENTATIVES

MAY 8, 2001

Mr. LAFALCE 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 part B of the Medicare Program of certain beta interferons and other biologicals and drugs approved by the Food and Drug Administration for treatment of multiple sclerosis.

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 “Multiple Sclerosis
5 Treatment Act of 2001”.

1 **SEC. 2. MEDICARE COVERAGE OF CERTAIN SELF-ADMINIS-**
2 **TERED BETA INTERFERONS AND OTHER**
3 **DRUGS AND BIOLOGICALS FOR PATIENTS**
4 **WITH MULTIPLE SCLEROSIS.**

5 (a) IN GENERAL.—Section 1861(s)(2) of the Social
6 Security Act (42 U.S.C. 1395x(s)(2)), as amended by the
7 Medicare, Medicaid, and SCHIP Benefits Improvement
8 and Protection Act of 2000, is amended—

9 (1) by striking “and” at the end of subparagraph
10 graph (U);

11 (2) by inserting “and” at the end of subparagraph
12 graph (V); and

13 (3) by adding at the end the following new sub-
14 paragraph:

15 “(W) the following biologicals or drugs ap-
16 proved by the Food and Drug Administration for
17 self-administration by patients with multiple scle-
18 rosis, subject to methods and standards established
19 by the Secretary by regulation for the safe and effec-
20 tive use of such biological or drug:

21 “(i) interferon beta 1-a,

22 “(ii) interferon beta 1-b,

23 “(iii) glatiramer acetate, and

24 “(iv) any other biological or drug found in
25 a review and approved by the Food and Drug
26 Administration to change the underlying course

1 of multiple sclerosis by such mechanisms as, for
2 example, slowing the progression or the relapse
3 rate of the disease;”

4 (b) REGULATIONS.—The Secretary of Health and
5 Human Services shall issue final regulations setting forth
6 methods and standards for the safe and effective use of
7 biologicals and drugs described in section 1861(s)(2)(W)
8 of the Social Security Act (as added by subsection (a)(3))
9 for purposes of carrying out such section. The Secretary
10 shall first issue such regulations—

11 (1) for biologicals and drugs described in
12 clauses (i) through (iii) of such section, by not later
13 than January 1, 2002; and

14 (2) for any biological or drug described in
15 clause (iv) of such section, by not later than (A) 60
16 days after the date of approval of the biological or
17 drug by the Food and Drug Administration, or (B)
18 January 1, 2002, whichever is later.

19 (c) EFFECTIVE DATE.—The amendments made by
20 subsection (a) shall apply to payments for items and serv-
21 ices furnished on or after January 1, 2002.

