105TH CONGRESS 1ST SESSION

H. R. 1018

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

March 11, 1997

Mr. Lafalce (for himself, Mr. Greenwood, Ms. Velázquez, Mr. Olver, Ms. Rivers, Mr. Frank of Massachusetts, Mr. Moran of Virginia, Mr. Ackerman, Mr. Sanders, Mr. Gutierrez, Mr. Frost, Mrs. Maloney of New York, Ms. Lofgren, Mr. Hinchey, Mr. Evans, Mr. Pastor, Ms. Slaughter, Mr. Skeen, Ms. Eshoo, Mr. Defazio, Mr. Foglietta, Mr. Gejdenson, and Mrs. Johnson of Connecticut) introduced the following bill; which was referred to the Committee on 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,

1 SECTION 1. SHORT TITLE. 2 This Act may be cited as the "Multiple Sclerosis 3 Treatment Act of 1997". SEC. 2. MEDICARE COVERAGE OF CERTAIN SELF-ADMINIS-4 5 BETA INTERFERONS AND OTHER TERED 6 DRUGS AND BIOLOGICALS FOR PATIENTS 7 WITH MULTIPLE SCLEROSIS. 8 (a) In General.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended— 9 (1) by striking "and" at the end of subpara-10 11 graphs (N) and (O), and 12 (2) by inserting after subparagraph (O) the fol-13 lowing new subparagraph: "(P) the following biologicals or drugs approved 14 15 by the Food and Drug Administration for self-ad-16 ministration by patients with multiple sclerosis, sub-17 ject to methods and standards established by the 18 Secretary by regulation for the safe and effective use 19 of such biological or drug: 20 "(i) interferon beta 1-a, 21 "(ii) interferon beta 1-b, 22 "(iii) glatiramer acetate, and 23 "(iv) any other biological or drug found in 24 a review and approved by the Food and Drug 25 Administration to change the underlying course

of multiple sclerosis by such mechanisms as, for

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1	example, slowing the progression or the relapse
2	rate of the disease; and"
3	(b) REGULATIONS.—The Secretary of Health and
4	Human Services shall issue final regulations setting forth
5	methods and standards for the safe and effective use of
6	biologicals and drugs described in section 1861(s)(2)(P)
7	of the Social Security Act (as inserted by subsection
8	(a)(2)) for purposes of carrying out such section. The Sec-
9	retary shall first issue such regulations—
10	(1) for biologicals and drugs described in
11	clauses (i) through (iii) of such section, by not later
12	than April 1, 1998; and
13	(2) for any biological or drug described in
14	clause (iv) of such section, by not later than (A) 60
15	days after the date of approval of the biological or
16	drug by the Food and Drug Administration, or (B)
17	April 1, 1998, whichever is later.
18	(c) Effective Date.—The amendments made by
19	subsection (a) shall apply to payments for items and serv-

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20 ices furnished on or after April 1, 1998.