

106TH CONGRESS
1ST SESSION

H. R. 2338

To require the Secretary of Health and Human Services to provide an individual who seeks to have a particular type of item or service to be covered benefit under the Medicare Program the option to meet with the Secretary in advance to develop a written agreement specifying the information necessary for the Secretary to make a national coverage determination under the Medicare Program.

IN THE HOUSE OF REPRESENTATIVES

JUNE 24, 1999

Mr. RAMSTAD introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Commerce, 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 require the Secretary of Health and Human Services to provide an individual who seeks to have a particular type of item or service to be covered benefit under the Medicare Program the option to meet with the Secretary in advance to develop a written agreement specifying the information necessary for the Secretary to make a national coverage determination 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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Medicare Coverage In-
3 formation Decision Act of 1999”.

4 **SEC. 2. MEETINGS REGARDING COVERAGE DECISIONS.**

5 (a) MEETINGS WITH THE SECRETARY.—

6 (1) IN GENERAL.—

7 (A) DEADLINE FOR MEETING.—In the
8 case of a person who submits to the Secretary
9 of Health and Human Services written notice
10 that the person intends to seek a national cov-
11 erage determination by the Secretary with re-
12 spect to whether a particular type or class of
13 items or services shall be covered under the
14 medicare program under title XVIII of the So-
15 cial Security Act (42 U.S.C. 1395 et seq.), the
16 Secretary shall meet with such person not later
17 than 30 days after receiving the request.

18 (B) PURPOSE OF MEETING.—Subject to
19 paragraph (3), the purpose of any meeting pur-
20 suant to paragraph (1) shall be to enter into a
21 written agreement that describes the specific in-
22 formation the Secretary requires in order to
23 make a national coverage determination with
24 respect to the particular type or class of items
25 or services under such title.

1 (2) CONTENT OF NOTICE.—A notice under
2 paragraph (1) shall include the following descrip-
3 tions:

4 (A) A description of the particular type or
5 class of items or services proposed to be covered
6 under such title.

7 (B) A description of the conditions for the
8 use of the particular type or class of items or
9 services.

10 (C) A description of the benefit categories
11 for which the particular type or class of items
12 or services is intended to be used.

13 (3) EXCEPTION.—If the Secretary determines
14 that a national coverage policy determination is not
15 appropriate or is premature for the particular class
16 of items or services that is the subject of the meet-
17 ing, the Secretary may decline to enter into an
18 agreement.

19 (b) PROVISIONS REGARDING AGREEMENTS.—

20 (1) IN GENERAL.—In the case of an agreement
21 entered into by the Secretary and such person under
22 subsection (a), not later than 30 days after the date
23 the agreement is entered into, the Secretary shall
24 transmit the written agreement to such person. The
25 written agreement shall be part of the administrative

1 record with respect to the national coverage deter-
2 mination of the particular type or class of items or
3 services proposed by such person to be covered
4 under such title.

5 (2) MODIFICATIONS.—

6 (A) IN GENERAL.—Subject to subpara-
7 graphs (B) and (C), any agreement entered into
8 under subsection (a) may not be modified.

9 (B) EXCEPTIONS.—Any such agreement
10 may be modified in any of the follow manners:

11 (i) In the case of a proposed modifica-
12 tion to the person by the Secretary, other
13 than a determination under clause (ii), the
14 person submits to the Secretary written
15 notice that the person agrees to the modi-
16 fication.

17 (ii) Subject to subparagraph (C), the
18 Secretary determines that a substantial
19 scientific issue essential to determining
20 whether the particular type of class of
21 items or services is reasonable and nec-
22 essary has been identified.

23 (C) SUBSTANTIAL SCIENTIFIC ISSUE.—A
24 modification to an agreement by reason of a de-
25 termination under subparagraph (B)(ii) shall be

1 in writing, and may only be made after the Sec-
2 retary has provided to such person an oppor-
3 tunity to meet with the Secretary to discuss the
4 scientific issue involved.

5 (c) TRADE SECRETS.—Subject to paragraph (2), any
6 information reported to or otherwise obtained by the Sec-
7 retary pursuant to this section which is exempt from dis-
8 closure pursuant to subsection (a) of section 552 of title
9 5, United States Code, by reason of subsection (b)(4) of
10 such section, shall be considered confidential and may not
11 be disclosed, except that such information may be dis-
12 closed to officers or employees of the Department of
13 Health and Human Services in their capacity as employees
14 in administering the medicare program under title XVIII
15 of the Social Security Act.

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