

112TH CONGRESS  
1ST SESSION

# H. R. 1845

To provide for a study on issues relating to access to intravenous immune globulin (IVIG) for Medicare beneficiaries in all care settings and a demonstration project to examine the benefits of providing coverage and payment for items and services necessary to administer IVIG in the home.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 11, 2011

Mr. BRADY of Texas (for himself, Ms. MATSUI, Mr. BURGESS, Mr. SARBANES, Mr. PAUL, Mr. VAN HOLLEN, Mr. TIBERI, Mr. RUPPERSBERGER, Mrs. BLACKBURN, Mr. SCHIFF, Ms. JENKINS, Mr. KIND, Ms. FUDGE, Ms. RICHARDSON, and Mr. RUSH) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and 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

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## A BILL

To provide for a study on issues relating to access to intravenous immune globulin (IVIG) for Medicare beneficiaries in all care settings and a demonstration project to examine the benefits of providing coverage and payment for items and services necessary to administer IVIG in the home.

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 IVIG Access  
3 Act”.

4 **SEC. 2. MEDICARE PATIENT IVIG ACCESS DEMONSTRATION**  
5 **PROJECT.**

6 (a) **ESTABLISHMENT.**—The Secretary shall establish  
7 and implement a demonstration project under title XVIII  
8 of the Social Security Act to evaluate the benefits of pro-  
9 viding payment for items and services needed for the ad-  
10 ministration, within the homes of Medicare beneficiaries,  
11 of intravenous immune globin for the treatment of pri-  
12 mary immune deficiency diseases.

13 (b) **DURATION AND SCOPE.**—

14 (1) **DURATION.**—Beginning not later than 6  
15 months after the date of enactment of this Act, the  
16 Secretary shall conduct the demonstration project  
17 for a period of 3 years.

18 (2) **SCOPE.**—The Secretary shall enroll not  
19 greater than 4,000 Medicare beneficiaries who have  
20 been diagnosed with primary immunodeficiency dis-  
21 ease for participation in the demonstration project.  
22 A Medicare beneficiary may participate in the dem-  
23 onstration project on a voluntary basis and may ter-  
24minate participation at any time.

25 (c) **REIMBURSEMENT.**—The Secretary shall establish  
26 an hourly rate for payment for items and services needed

1 for the administration of intravenous immune globin based  
2 on the low-utilization payment adjustment under the pro-  
3 spective payment system for home health services estab-  
4 lished under section 1895 of the Social Security Act (42  
5 U.S.C. 1395fff).

6 (d) STUDY AND REPORT TO CONGRESS.—

7 (1) INTERIM EVALUATION AND REPORT.—Not  
8 later than 24 months after the date of enactment of  
9 this Act, the Secretary shall submit to Congress a  
10 report that contains the following:

11 (A) An interim evaluation of the impact of  
12 the demonstration project on access for Medi-  
13 care beneficiaries to items and services needed  
14 for the administration of intravenous immune  
15 globin within the home.

16 (B) An analysis of the appropriateness of  
17 implementing a new methodology for payment  
18 for intravenous immune globulins in all care  
19 settings under part B of title XVIII of the So-  
20 cial Security Act (42 U.S.C. 1395k et seq.).

21 (C) An analysis of the feasibility of reduc-  
22 ing the lag time with respect to data used to  
23 determine the average sales price under section  
24 1847A of the Social Security Act (42 U.S.C.  
25 1395w-3a).

1 (D) An update to the report entitled  
2 “Analysis of Supply, Distribution, Demand, and  
3 Access Issues Associated with Immune Globulin  
4 Intravenous (IGIV)”, issued in February 2007  
5 by the Office of the Assistant Secretary for  
6 Planning and Evaluation of the Department of  
7 Health and Human Services.

8 (2) FINAL EVALUATION AND REPORT.—Not  
9 later than July 1, 2015, the Secretary shall submit  
10 to Congress a report that contains a final evaluation  
11 of the impact of the demonstration project on access  
12 for Medicare beneficiaries to items and services  
13 needed for the administration of intravenous im-  
14 mune globin within the home.

15 (e) OFFSET.—

16 (1) IN GENERAL.—Section 1861(n) of the So-  
17 cial Security Act (42 U.S.C. 1395x(n)) is amended  
18 by adding at the end the following: “Such term in-  
19 cludes disposable drug delivery systems, including  
20 elastomeric infusion pumps, for the treatment of  
21 colorectal cancer.”.

22 (2) EFFECTIVE DATE.—The amendment made  
23 by paragraph (1) shall apply to items furnished on  
24 or after the date of enactment of this Act.

25 (f) DEFINITIONS.—In this Act:

1           (1) DEMONSTRATION PROJECT.—The term  
2           “demonstration project” means the demonstration  
3           project conducted under this Act.

4           (2) MEDICARE BENEFICIARY.—The term  
5           “Medicare beneficiary” means an individual who is  
6           entitled to, or enrolled for, benefits under part A of  
7           title XVIII of the Social Security Act or enrolled for  
8           benefits under part B of such title.

9           (3) SECRETARY.—The term “Secretary” means  
10          the Secretary of Health and Human Services.

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