

112TH CONGRESS  
1ST SESSION

# S. 960

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 SENATE OF THE UNITED STATES

MAY 12, 2011

Mr. KERRY (for himself, Mr. ALEXANDER, and Mr. WYDEN) introduced the following bill; which was read twice and referred to the Committee on Finance

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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,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medicare IVIG Access  
5 Act”.

1 **SEC. 2. MEDICARE PATIENT IVIG ACCESS DEMONSTRATION**  
2 **PROJECT.**

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

10 (b) DURATION AND SCOPE.—

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

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

22 (c) REIMBURSEMENT.—The Secretary shall establish  
23 an hourly rate for payment for items and services needed  
24 for the administration of intravenous immune globin based  
25 on the low-utilization payment adjustment under the pro-  
26 spective payment system for home health services estab-

1 lished under section 1895 of the Social Security Act (42  
2 U.S.C. 1395fff).

3 (d) STUDY AND REPORT TO CONGRESS.—

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

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

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

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

23 (D) An update to the report entitled  
24 “Analysis of Supply, Distribution, Demand, and  
25 Access Issues Associated with Immune Globulin

1           Intravenous (IGIV)”, issued in February 2007  
2           by the Office of the Assistant Secretary for  
3           Planning and Evaluation of the Department of  
4           Health and Human Services.

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

12          (e) OFFSET.—

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

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

22          (f) DEFINITIONS.—In this Act:

23           (1) DEMONSTRATION PROJECT.—The term  
24          “demonstration project” means the demonstration  
25          project conducted under this Act.

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

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

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