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.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the ''Medicare IVIG Access Act''.

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

(a) ESTABLISHMENT.—The Secretary shall establish and implement a demonstration project under title XVIII of the Social Security Act to evaluate the benefits of providing payment for items and services needed for the administration, within the homes of Medicare beneficiaries, of intravenous immune globin for the treatment of primary immune deficiency diseases.

(b) DURATION AND SCOPE.—

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

(2) SCOPE.—The Secretary shall enroll not greater than 4,000 Medicare beneficiaries who have been diagnosed with primary immunodeficiency disease for participation in the demonstration project. A Medicare beneficiary may participate in the demonstration project on a voluntary basis and may terminate participation at any time.

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

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

(d) STUDY AND REPORT TO CONGRESS.—

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

(A) An interim evaluation of the impact of the demonstration project on access for Medicare beneficiaries to items and services needed for the administration of intravenous immune globin within the home.

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

(C) An analysis of the feasibility of reducing the lag time with respect to data used to determine the average sales price under section 1847A of the Social Security Act (42 U.S.C. 1395w–3a).

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

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

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

(e) OFFSET.—

(1) IN GENERAL.—Section 1861(n) of the Social Security Act (42 U.S.C. 1395x(n)) is amended by adding at the end the following: ''Such term includes disposable drug delivery systems, including elastomeric infusion pumps, for the treatment of colorectal cancer.''.

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

(f) DEFINITIONS.—In this Act:

(1) DEMONSTRATION PROJECT.—The term ''demonstration project'' means the demonstration project conducted under this Act.

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

(3) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

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