### 111TH CONGRESS 2D SESSION

# H. R. 5597

To establish a Medicare patient IVIG access demonstration project.

### IN THE HOUSE OF REPRESENTATIVES

June 24, 2010

Ms. Matsui (for herself, Mr. Rush, Mr. Braley of Iowa, Mr. Van Hollen, Mr. Gerlach, Mr. Terry, Mr. Brady of Texas, and Mr. Pitts) 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

## A BILL

To establish a Medicare patient IVIG access demonstration project.

- 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. MEDICARE PATIENT IVIG ACCESS DEMONSTRA-
- 4 TION PROJECT.
- 5 (a) Establishment.—The Secretary shall establish
- 6 and implement a demonstration project under title XVIII
- 7 of the Social Security Act to evaluate the benefits of pro-
- 8 viding payment for items and services needed for the ad-

- ministration, within the homes of Medicare beneficiaries, of intravenous immune globin for the treatment of pri-3 mary immune deficiency diseases. 4 (b) Duration and Scope.— (1) Duration.—Beginning not later than Jan-6 uary 1, 2011, the Secretary shall conduct the dem-7 onstration project for a period of 3 years. 8 (2) Scope.—The Secretary shall enroll not 9 greater than 4,000 Medicare beneficiaries who have 10 been diagnosed with primary immunodeficiency dis-11 ease for participation in the demonstration project. 12 A Medicare beneficiary may participate in the dem-13 onstration project on a voluntary basis and may ter-14 minate participation at any time. 15 (c) Reimbursement.—The Secretary shall establish an hourly rate for payment for items and services needed 16 for the administration of intravenous immune globin based 18 on the low-utilization payment adjustment under the prospective payment system for home health services estab-19 lished under section 1895 of the Social Security Act (42) 20 21 U.S.C. 1395fff). 22 (d) STUDY AND REPORT TO CONGRESS.—
- 23 (1) Interim Evaluation and Report.—Not 24 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 feasability 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.

1 (2) Final evaluation and report.—Not
2 later than July 1, 2014, the Secretary shall submit
3 to Congress a report that contains a final evaluation
4 of the impact of the demonstration project on access
5 for Medicare beneficiaries to items and services
6 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.

### 18 (f) Definitions.—In this section:

- (1) Demonstration project.—The term "demonstration project" means the demonstration project conducted under this section.
- (2) Medicare beneficiary" means an individual who is entitled to, or enrolled for, benefits under part A of

- 1 title XVIII of the Social Security Act or enrolled for
- 2 benefits under part B of such title.
- 3 (3) Secretary.—The term "Secretary" means
- 4 the Secretary of Health and Human Services.

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