

110TH CONGRESS  
1ST SESSION

**H. R.** \_\_\_\_\_

To amend title XVIII of the Social Security Act to improve access of Medicare beneficiaries to immune globulins.

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IN THE HOUSE OF REPRESENTATIVES

Mr. BRADY of Texas introduced the following bill; which was referred to the Committee on \_\_\_\_\_

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**A BILL**

To amend title XVIII of the Social Security Act to improve access of Medicare beneficiaries to immune globulins.

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; TABLE OF CONTENTS.**

4       (a) **SHORT TITLE.**—This Act may be cited as the  
5 “Medicare IVIG Access Act of 2007”.

6       (b) **TABLE OF CONTENTS.**—The table of contents of  
7 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Findings.
- Sec. 3. Medicare payment for immune globulins.
- Sec. 4. Coverage and payment of intravenous immune globulin in the home.
- Sec. 5. Patient access surveys and reports.

1 **SEC. 2. FINDINGS.**

2 (a) FINDINGS.—Congress finds the following:

3 (1) Approximately 10,000 Medicare bene-  
4 ficiaries have a primary immune deficiency disease  
5 (PIDD), a class of disorders in which there is a ge-  
6 netic or intrinsic defect in the human immune sys-  
7 tem, and receive treatment through intravenous in-  
8 fusions of gammaglobulin (IVIG), the only effective  
9 treatment for their condition. For them, it is a life-  
10 saving therapy.

11 (2) IVIG differs from traditional pharma-  
12 ceuticals and other biological products because of the  
13 high costs associated with acquiring human plasma,  
14 the complexity of its manufacturing process, and  
15 critical quality measures needed to assure its safety  
16 for patients. The report of the Office of the Assist-  
17 ant Secretary for Planning and Evaluation (ASPE),  
18 Department of Health and Human Services, Anal-  
19 ysis of Supply, Distribution, Demand, and Access  
20 Issues Associated with Immune Globulin Intra-  
21 venous (IGIV), issued in May 2007, found that  
22 IGIV manufacturing is complex and requires sub-  
23 stantial upfront cash outlay and planning and takes  
24 between 7 and 12 months from plasma collection at  
25 donor centers to FDA lot release.

1           (3) IVIG therapies are not interchangeable,  
2           with individual patients tolerating one brand of  
3           IVIG better than other brands because of differences  
4           in the manufacturing process used by companies  
5           producing IVIG.

6           (4) The Medicare Prescription Drug, Improve-  
7           ment, and Modernization Act of 2003 changed Medi-  
8           care's reimbursement methodology for IVIG from  
9           average whole price (AWP) to average sales price  
10          plus 6 percent (ASP+6), effective January 1, 2005,  
11          for physicians, and January 1, 2006, for hospital  
12          outpatient departments, thereby reducing reimburse-  
13          ment rates paid to these providers of IVIG on behalf  
14          of Medicare beneficiaries.

15          (5) An Office of the Inspector General (OIG)  
16          April 2007 report, Intravenous Immune Globulin:  
17          Medicare Payment and Availability, found that  
18          Medicare reimbursement for IVIG was inadequate to  
19          cover the cost many providers must pay for the  
20          product. During the third quarter of 2006, 44 per-  
21          cent of IVIG sales to hospitals and 41 percent of  
22          sales to physicians by the three largest distributors  
23          occurred at prices above Medicare payment amounts.

24          (6) The OIG also reported that 61 percent of  
25          responding physicians indicated that they had sent

1 patients to hospitals for IVIG treatment, largely be-  
2 cause of their inability to purchase IVIG at prices  
3 below the Medicare payment amounts. In addition,  
4 OIG found that some physicians had stopped pro-  
5 viding IVIG to Medicare beneficiaries altogether.

6 (7) The OIG's 2007 report concluded that  
7 whatever improvement some providers saw in the re-  
8 lationship of Medicare reimbursement for IVIG to  
9 prices paid during the first three quarters of 2006  
10 would be eroded if manufacturers were to increase  
11 prices for IVIG in the future.

12 (8) The Centers for Medicare & Medicaid Serv-  
13 ices, in recognition of dislocations experienced by pa-  
14 tients and providers in obtaining IVIG since the  
15 change to the ASP+6 reimbursement methodology,  
16 has provided during 2006 and 2007 a temporary ad-  
17 ditional payment for IVIG preadministration-related  
18 services to compensate physicians and hospital out-  
19 patient departments for the extra resources they  
20 have had to expend in locating and obtaining appro-  
21 priate IVIG products and in scheduling patient infu-  
22 sions.

23 (9) The ASPE report, Analysis of Supply, Dis-  
24 tribution, Demand, and Access Issues Associated  
25 with Immune Globulin Intravenous (IGIV), found

1 that Medicare’s IVIG home infusion benefit is not  
2 designed to reimburse for more than the cost of  
3 IVIG and does not cover the cost of infusion services  
4 (for example, nursing and clinical services and sup-  
5 plies) in the home. As a consequence, the report  
6 found that home infusion providers generally do not  
7 accept new PIDD patients with only Medicare cov-  
8 erage. These limitations in service are caused by  
9 health care providers (A) not being able to acquire  
10 IVIG at prices at or below the Medicare part B re-  
11 imbursement level, and(B) not being reimbursed for  
12 the infusion services provided by a nurse.

13 (10) Access to home infusion of IVIG for PIDD  
14 patients will reduce their exposure to infections at a  
15 time when their antibodies are compromised and will  
16 improve the quality of their care and their health.

17 **SEC. 3. MEDICARE PAYMENT FOR IMMUNE GLOBULINS.**

18 (a) IN GENERAL.—Section 1842(o)(1)(E) of the So-  
19 cial Security Act (42 U.S.C. 1395u(o)(1)(E)) is amend-  
20 ed—

21 (1) in paragraph (1)(E)(ii), by inserting before  
22 the period the following: “, plus an additional  
23 amount (if applicable) under paragraph (7)”;

1           (2) in paragraph (7), by striking “(6)” and in-  
2           serting “(7)” and by redesignating it as paragraph  
3           (8); and

4           (3) by inserting after paragraph (6) the fol-  
5           lowing new paragraph:

6           “(7)(A) Not later than 6 months after the date  
7           of the enactment of the Medicare IVIG Access Act  
8           of 2007, the Secretary shall—

9                   “(i) collect data on the differences, if any,  
10                   between payments to physicians for immune  
11                   globulins under paragraph (1)(E)(ii) and costs  
12                   incurred by physicians for furnishing these  
13                   products; and

14                   “(ii) review available data, including survey  
15                   data presented by patient organizations, med-  
16                   ical specialty societies, and pharmacists, on the  
17                   access of individuals eligible for services under  
18                   this part to immune globulins.

19           “(B) Upon completion of the review and collec-  
20           tion of data under subparagraph (A), the Secretary  
21           shall provide, if appropriate, to physicians furnishing  
22           immune globulins, a payment, in addition to the  
23           payment provided for in paragraph (1)(E)(ii), for all  
24           items and services related to the furnishing of im-

1       mune globulins, in an amount that the Secretary de-  
2       termines to be appropriate.

3               “(C) In the case of immune globulins furnished  
4       on or after January 1, 2007, the Secretary shall  
5       continue the preadministration-related services pay-  
6       ment established under the Final Physician Fee  
7       Schedule Rule issued by the Centers for Medicare &  
8       Medicaid Services on November 1, 2006 (CMS-  
9       1321-FC), until such time as the Secretary deter-  
10      mines that payment for immune globulins is ade-  
11      quate or until a new payment methodology is imple-  
12      mented.”.

13       (b) AS PART OF HOSPITAL OUTPATIENT SERV-  
14      ICES.—Section 1833(t)(14) of such Act (42 U.S.C.  
15      1395l(t)(14)) is amended—

16               (1) in subparagraph (A)(iii), by striking “sub-  
17      paragraph (E)” and inserting “subparagraphs (E)  
18      and (I)”;

19               (2) by adding at the end the following new sub-  
20      paragraph:

21                       “(I) ADDITIONAL PAYMENT FOR IMMUNE  
22                       GLOBULINS.—

23                               “(i) DATA COLLECTION AND RE-  
24                               VIEW.—Not later than 6 months after the  
25                               date of the enactment of the Medicare

1 IVIG Access Act of 2007, the Secretary  
2 shall—

3 “(I) review available data, includ-  
4 ing survey data presented by patient  
5 organizations, medical specialty soci-  
6 eties, and pharmacists, on the access  
7 of individuals eligible for services  
8 under this part to immune globulins;  
9 and

10 “(II) collect data on the dif-  
11 ferences, if any, between payments for  
12 immune globulins under subparagraph  
13 (A)(iii) and costs incurred for fur-  
14 nishing these products.

15 “(ii) ADDITIONAL PAYMENT AUTHOR-  
16 ITY.—Upon completion of the review and  
17 collection of data under clause (i), the Sec-  
18 retary shall provide, if appropriate, to hos-  
19 pitals furnishing immune globulins as part  
20 of a covered OPD service, a payment, in  
21 addition to the payment provided for under  
22 subparagraph (A)(iii), for all items and  
23 services related to the furnishing of im-  
24 mune globulins, in an amount that the  
25 Secretary determines to be appropriate.

1           “(iii) CONTINUATION OF SPECIAL  
2           PAYMENT RULE.—In the case of immune  
3           globulins furnished on or after January 1,  
4           2007, the Secretary shall continue the  
5           preadministration-related services payment  
6           established under the Final Hospital Out-  
7           patient Rule issued by the Centers for  
8           Medicare & Medicaid Services November 1,  
9           2006 (CMS-1506-FC), until such time as  
10          the Secretary determines that payment for  
11          immune globulins is adequate or until a  
12          new payment methodology is imple-  
13          mented.”.

14 **SEC. 4. COVERAGE AND PAYMENT OF INTRAVENOUS IM-**  
15 **MUNE GLOBULIN IN THE HOME.**

16          (a) INCLUDING COVERAGE OF ADMINISTRATION.—  
17          Section 1861(zz) of the Social Security Act (42 U.S.C.  
18          1395x(zz)) is amended by striking “but not including  
19          items or services related to the administration of the deriv-  
20          ative”.

21          (b) PAYMENT FOR INTRAVENOUS IMMUNE GLOBULIN  
22          ADMINISTRATION IN THE HOME.—Section 1834 of such  
23          Act (42 U.S.C. 1395m) is amended by adding at the end  
24          the following new subsection:

1           “(n) PAYMENT FOR INTRAVENOUS IMMUNE GLOB-  
2 ULIN IN THE HOME.—The Secretary shall review available  
3 published and unpublished data and information, includ-  
4 ing the Study of Intravenous Immune Globulin Adminis-  
5 tration Options: Safety, Access, and Cost Issues (CMS  
6 Contract #500-95-0059), on confirming the appropriate-  
7 ness of administration of intravenous immune globulin in  
8 the home setting, and calculate the amount, in addition  
9 to that made under 1842(o)(1)(E)(iii) for immune  
10 globulins, that should be paid to providers for clinical,  
11 compliance, and complication management services for en-  
12 suring safe and efficacious delivery of immune globulins  
13 in the home setting under 1861(s)(2)(Z). The Secretary  
14 shall pay such amounts no later than January 1, 2008.”.

15           (c) APPLICATION OF CRIMINAL RECORD REQUEST  
16 PROVISIONS TO IVIG IN-HOME PROVIDERS.—Section  
17 124(i)(1) of the Departments of Commerce, Justice,  
18 State, the Judiciary, and Related Agencies Appropriations  
19 Act, 1999 (as contained in section 1(b) of Public Law 105-  
20 277; 112 Stat. 2681-74) is amended by adding at the end  
21 the following: “Such term includes an entity providing in-  
22 travenous immune globulin under part B of title XVIII  
23 of the Social Security Act in a home.”.

1 (d) EFFECTIVE DATE.—The amendments made by  
2 subsections (a) and (b) shall apply to intravenous immune  
3 globulin administered on or after January 1, 2008.

4 **SEC. 5. PATIENT ACCESS SURVEYS AND REPORTS.**

5 (a) SURVEYS.—The Secretary of Health and Human  
6 Services shall enter into contracts with qualified organiza-  
7 tions or entities for the completion, not later than 3 years  
8 after the date of the enactment of this Act, of two surveys  
9 of Medicare and non-Medicare patients who need immune  
10 globulins for the purpose of measuring changes in patient  
11 access to those products (and providers furnishing those  
12 products), as well as changes in the health care status of  
13 those patients.

14 (b) SURVEY REPORTS.—Each of the surveys shall in-  
15 clude a report to the Secretary and the Committees on  
16 Energy and Commerce and Ways and Means of the House  
17 of Representatives and the Committee on Finance of the  
18 Senate on findings from the survey, as well as a discussion  
19 of reasons for observed changes, if any.

20 (c) CONGRESSIONAL REPORTS.—On the basis of  
21 findings from such surveys, the Secretary shall submit to  
22 Congress reports that include recommendations on nec-  
23 essary adjustments in payments for immune globulins  
24 under the Medicare program in order to assure beneficiary  
25 access to those products and providers that furnish those

1 products. The first such report shall be submitted no later  
2 than 2 years after the date of the enactment of this Act  
3 and the second report no later than four years after such  
4 date.