

110TH CONGRESS  
1ST SESSION

# H. R. 2914

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

JUNE 28, 2007

Mr. BRADY of Texas (for himself, Mr. ISRAEL, Mrs. BLACKBURN, Mr. BURGESS, Mrs. CUBIN, Mr. ENGLISH of Pennsylvania, Mr. HERGER, Mr. HINCHEY, Mr. MEEKS of New York, Mr. MCNULTY, Mr. NUNES, Mr. PAUL, Mr. RAMSTAD, Mr. SESSIONS, Mrs. TAUSCHER, Ms. ROYBAL-ALLARD, Mr. SMITH of New Jersey, and Mr. YOUNG of Florida) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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 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”.

1 (b) TABLE OF CONTENTS.—The table of contents of  
2 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.

3 **SEC. 2. FINDINGS.**

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

5 (1) Intravenous immune globulin (IVIG) is a  
6 human blood plasma derived product, which over the  
7 past 25 years has become an invaluable therapy for  
8 many primary immunodeficiency diseases, as well as  
9 a number of neurological, autoimmune, and other  
10 chronic conditions and illnesses. For many of these  
11 disorders, IVIG is the most effective and viable  
12 treatment available, and has dramatically improved  
13 the quality of life for persons with these conditions  
14 and has become a life-saving therapy for many.

15 (2) The Food and Drug Administration (FDA)  
16 recognizes each IVIG brand as a unique biologic.  
17 The differences in basic fractionation and the addi-  
18 tion of various modifications for further purification,  
19 stabilization and virus inactivation/removal yield  
20 clearly different biological products. As a result,  
21 IVIG therapies are not interchangeable, with patient  
22 tolerance differing from one IVIG brand to another.

1           (3) The report of the Office of the Assistant  
2 Secretary for Planning and Evaluation (ASPE), De-  
3 partment of Health and Human Services (DHHS),  
4 “Analysis of Supply, Distribution, Demand, and Ac-  
5 cess Issues Associated with Immune Globulin Intra-  
6 venous (IGIV)”, issued in May 2007, found that  
7 IVIG manufacturing is complex and requires sub-  
8 stantial upfront cash outlay and planning and takes  
9 between seven and 12 months from plasma collection  
10 at donor centers to FDA lot release.

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

20           (5) An Office of the Inspector General (OIG)  
21 April 2007 report, Intravenous Immune Globulin:  
22 Medicare Payment and Availability, found that  
23 Medicare reimbursement for IVIG was inadequate to  
24 cover the cost many providers must pay for the  
25 product. During the third quarter of 2006, 44 per-

1 cent of IVIG sales to hospitals and 41 percent of  
2 sales to physicians by the three largest distributors  
3 occurred at prices above Medicare payment amounts.

4 (6) The ASPE report notes that after the new  
5 reimbursement rules for physicians was instituted in  
6 2005, 42 percent of Medicare beneficiaries who had  
7 received their IVIG treatment in their physician's of-  
8 fice at the end of 2004 were shifted to the hospital  
9 outpatient setting by the beginning of 2006. This  
10 shift in site of care has resulted in lack of continuity  
11 of care and adverse impact on health outcomes and  
12 quality of life.

13 (7) The OIG also reported that 61 percent of  
14 responding physicians indicated that they had sent  
15 patients to hospitals for IVIG treatment, largely be-  
16 cause of their inability to purchase IVIG at prices  
17 below the Medicare payment amounts. In addition,  
18 OIG found that some physicians had stopped pro-  
19 viding IVIG to Medicare beneficiaries altogether.

20 (8) The OIG's 2007 report concluded that  
21 whatever improvement some providers saw in the re-  
22 lationship of Medicare reimbursement for IVIG to  
23 prices paid during the first three quarters of 2006  
24 would be eroded if manufacturers were to increase  
25 prices for IVIG in the future.

1           (9) The Centers for Medicare & Medicaid Serv-  
2           ices, in recognition of dislocations experienced by pa-  
3           tients and providers in obtaining IVIG since the  
4           change to the ASP+6 reimbursement methodology,  
5           has provided during 2006 and 2007 a temporary ad-  
6           ditional payment for IVIG preadministration-related  
7           services to compensate physicians and hospital out-  
8           patient departments for the extra resources they  
9           have had to expend in locating and obtaining appro-  
10          prium IVIG products and in scheduling patient infu-  
11          sions.

12          (10) Approximately 10,000 Medicare bene-  
13          ficiaries receive IVIG treatment for their primary  
14          immunodeficiency disease in a variety of different  
15          settings. They have no other effective treatment for  
16          their condition.

17          (11) The Medicare Modernization Act of 2003  
18          (MMA) established an IVIG home infusion benefit  
19          for persons with primary immunodeficiency disease  
20          (PIDD), paying only for IVIG and specifically ex-  
21          cluding coverage of items and services related to ad-  
22          ministration of the product.

23          (12) The ASPE report, Analysis of Supply,  
24          Distribution, 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 (13) Access to home infusion of IVIG for PIDD  
14 patients, who have a genetic or intrinsic defect in  
15 their human immune system, will reduce their expo-  
16 sure to infections at a time when their antibodies are  
17 compromised and will improve the quality of their  
18 care and their health.

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

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

23 (1) in paragraph (1)(E)(ii), by inserting before  
24 the period the following: “, plus an additional  
25 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 members of the IVIG com-  
16                   munity on the access of individuals eligible for  
17                   services under this part to immune globulins.

18           “(B) Upon completion of the review and collec-  
19           tion of data under subparagraph (A), and not later  
20           than 7 months after the date of the enactment of  
21           this paragraph, the Secretary shall provide, if appro-  
22           priate, to physicians furnishing immune globulins, a  
23           payment, in addition to the payment provided for in  
24           paragraph (1)(E)(ii), for all items related to the fur-

1 nishing of immune globulins, in an amount that the  
2 Secretary determines 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)”; and

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 members  
5 of the IVIG community, on the access  
6 of individuals eligible for services  
7 under this part to immune globulins;  
8 and

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

14 “(ii) ADDITIONAL PAYMENT AUTHOR-  
15 ITY.—Upon completion of the review and  
16 collection of data under clause (i), and not  
17 later than 7 months after the date of the  
18 enactment of this subparagraph, the Sec-  
19 retary shall provide, if appropriate, to hos-  
20 pitals furnishing immune globulins as part  
21 of a covered OPD service, a payment, in  
22 addition to the payment provided for under  
23 subparagraph (A)(iii), for all items related  
24 to the furnishing of immune globulins, in

1 an amount that the Secretary determines  
2 to be appropriate.

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

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

18 (a) INCLUDING COVERAGE OF ADMINISTRATION.—

19 (1) IN GENERAL.—Section 1861 of the Social  
20 Security Act (42 U.S.C. 1395x) is amended—

21 (A) in subsection (s)(2)(Z), by inserting  
22 before the semicolon at the end the following: “,  
23 regardless of whether the individual receiving  
24 the globulin is eligible to receive home health  
25 services under this title”; and

1 (B) in subsection (zz), by striking “but not  
2 including items or services related to the admin-  
3 istration of the derivative”.

4 (2) CONFORMING HOME HEALTH AMEND-  
5 MENT.—Section 1814(a) of such Act (42 U.S.C.  
6 1395f(a)) is amended by adding at the end the fol-  
7 lowing: “An individual eligible for intravenous im-  
8 mune globulin under section 1861(s)(2)(Z) shall not  
9 be considered eligible for home health services under  
10 paragraph (2)(C) or section 1835(a)(2)(A) solely on  
11 the basis of meeting the requirements of such sub-  
12 section or section 1861(zz).”.

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

17 “(n) PAYMENT FOR INTRAVENOUS IMMUNE GLOB-  
18 ULIN IN THE HOME.—The Secretary shall review available  
19 published and unpublished data and information, includ-  
20 ing the Study of Intravenous Immune Globulin Adminis-  
21 tration Options: Safety, Access, and Cost Issues (CMS  
22 Contract #500–95–0059), on confirming the appropriate-  
23 ness of administration of intravenous immune globulin in  
24 the home setting, and (as appropriate) calculate the  
25 amount, in addition to that made under section

1 1842(o)(1)(E)(ii) for immune globulins, that should be  
2 paid to providers for clinical, compliance, and complication  
3 management services for ensuring safe and efficacious de-  
4 livery of immune globulins in the home setting under  
5 1861(s)(2)(Z). The Secretary shall pay such amounts no  
6 later than January 1, 2008.”.

7 (c) APPLICATION OF CRIMINAL RECORD REQUEST  
8 PROVISIONS TO IVIG IN-HOME PROVIDERS.—Section  
9 124(i)(1) of the Departments of Commerce, Justice,  
10 State, the Judiciary, and Related Agencies Appropriations  
11 Act, 1999 (as contained in section 1(b) of Public Law  
12 105–277; 112 Stat. 2681–74) is amended by adding at  
13 the end the following: “Such term includes an entity pro-  
14 viding intravenous immune globulin under part B of title  
15 XVIII of the Social Security Act in a home.”.

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

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

20 (a) SURVEYS.—The Secretary of Health and Human  
21 Services shall conduct, not later than 3 years after the  
22 date of the enactment of this Act, two surveys of Medicare  
23 and non-Medicare patients who need immune globulins for  
24 the purpose of measuring changes in patient access to  
25 those products (and providers furnishing those products),

1 as well as changes in the health care status of those pa-  
2 tients. The Secretary may enter into contracts with orga-  
3 nizations or entities qualified to conduct such surveys.

4 (b) SURVEY REPORTS.—Each of the surveys shall in-  
5 clude a report to the Secretary and the Committees on  
6 Energy and Commerce and Ways and Means of the House  
7 of Representatives and the Committee on Finance of the  
8 Senate on findings from the survey, as well as a discussion  
9 of reasons for observed changes, if any.

10 (c) CONGRESSIONAL REPORTS.—On the basis of  
11 findings from such surveys, the Secretary shall submit to  
12 Congress reports that include recommendations on nec-  
13 essary adjustments in payments for immune globulins  
14 under the Medicare program in order to assure beneficiary  
15 access to those products and providers that furnish those  
16 products. The first such report shall be submitted no later  
17 than 2 years after the date of the enactment of this Act  
18 and the second report no later than four years after such  
19 date.

○