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

IN THE HOUSE OF REPRESENTATIVES

APRIL 21, 2009

Mr. ISRAEL (for himself, Mr. BRADY of Texas, Ms. SCHWARTZ, Mr. MOORE of Kansas, Mr. MCGOVERN, Mrs. BLACKBURN, and Mr. GRIJALVA) 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

A BILL

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

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 Patient IVIG Access Act of 2009”.

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 intravenous immune globulins (IVIG).
Sec. 4. Coverage and payment of intravenous immune globulin in the home.
Sec. 5. Collection of data and review of complexity codes for physician administration of IVIG.
Sec. 6. Reports.
Sec. 7. Medicare coverage of disposable pumps as items of durable medical equipment in certain cases.

1 **SEC. 2. FINDINGS.**

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

3 (1) The 2001 report of the Medicare Payment
4 Advisory Commission to Congress states that “to
5 help ensure beneficiaries’ access to high-quality care,
6 Medicare payments should correspond to the cost ef-
7 ficient providers incur in furnishing this care”. Pay-
8 ments that do not meet this objective may create
9 barriers to access.

10 (2) Intravenous immune globulin (IVIG) is a
11 human blood plasma derived product, which over the
12 past 25 years has become an invaluable therapy for
13 many chronic conditions and illnesses, including pri-
14 mary immunodeficiency diseases, autoimmune and
15 neurological disorders. For many of these disorders,
16 IVIG is the most effective and viable treatment
17 available, and has dramatically improved the quality
18 of life for persons with these conditions and has be-
19 come a life-saving therapy for many.

20 (3) The Food and Drug Administration (FDA)
21 recognizes each IVIG brand as a unique biologic.

1 The differences in basic fractionation and the addi-
2 tion of various modifications for further purification,
3 stabilization and virus inactivation/removal yield
4 clearly different biological products. As a result,
5 IVIG therapies are not interchangeable, with patient
6 tolerance differing from one IVIG brand to another.

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

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

1 (6) An Office of the Inspector General (OIG)
2 April 2007 report, Intravenous Immune Globulin:
3 Medicare Payment and Availability, found that
4 Medicare reimbursement for IVIG was inadequate to
5 cover the cost many providers must pay for the
6 product. During the third quarter of 2006, 44 per-
7 cent of IVIG sales to hospitals and 41 percent of
8 sales to physicians by the three largest distributors
9 occurred at prices above Medicare payment amounts.

10 (7) The ASPE report notes that after the new
11 reimbursement rules for physicians were instituted
12 in 2005, 42 percent of Medicare beneficiaries who
13 had received their IVIG treatment in their physi-
14 cian's office at the end of 2004 were shifted to the
15 hospital outpatient setting by the beginning of 2006.
16 This shift in site of care has resulted in lack of con-
17 tinuity of care and adverse impact on health out-
18 comes and quality of life.

19 (8) The OIG also reported that 61 percent of
20 responding physicians indicated that they had sent
21 patients to hospitals for IVIG treatment, largely be-
22 cause of their inability to purchase IVIG at prices
23 below the Medicare payment amounts. In addition,
24 OIG found that some physicians had stopped pro-
25 viding IVIG to Medicare beneficiaries altogether.

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

7 (10) The Centers for Medicare & Medicaid
8 Services, in recognition of dislocations experienced
9 by patients and providers in obtaining IVIG since
10 the change to the ASP+6 reimbursement method-
11 ology, has provided during 2006 and 2007 a tem-
12 porary additional payment for IVIG
13 preadministration-related services to compensate
14 physicians and hospital outpatient departments for
15 the extra resources they have had to expend in locat-
16 ing and obtaining appropriate IVIG products and in
17 scheduling patient infusions.

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

24 (12) The ASPE report, Analysis of Supply,
25 Distribution, Demand, and Access Issues Associated

1 with Immune Globulin Intravenous (IGIV), found
2 that Medicare's IVIG home infusion benefit is not
3 designed to reimburse for more than the cost of
4 IVIG and does not cover the cost of infusion services
5 (for example, nursing and clinical services and sup-
6 plies) in the home. As a consequence, the report
7 found that home infusion providers generally do not
8 accept new PIDD patients with only Medicare cov-
9 erage. These limitations in service are caused by
10 health care providers—

11 (A) not being able to acquire IVIG at
12 prices at or below the Medicare part B reim-
13 bursement level; and

14 (B) not being reimbursed for the infusion
15 services provided by a nurse.

16 (13) Physicians administering IVIG to Medi-
17 care beneficiaries are reimbursed at the same low
18 complexity level as the administration of antibiotics.
19 However, the administration of IVIG requires special
20 preparation and handling, involves significant pa-
21 tient risk, and prolonged nursing time to monitor
22 the patient during infusion.

1 **SEC. 3. MEDICARE PAYMENT FOR INTRAVENOUS IMMUNE**
2 **GLOBULINS (IVIG).**

3 (a) IN GENERAL.—Section 1842(o) of the Social Se-
4 curity Act (42 U.S.C. 1395u(o)) is amended—

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

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

11 (3) by inserting after paragraph (6) the fol-
12 lowing new paragraph:

13 “(7)(A) Not later than 6 months after the date
14 of the enactment of the Medicare Patient IVIG Ac-
15 cess Act of 2009, the Secretary shall—

16 “(i) collect data on the differences, if any,
17 between payments to physicians for immune
18 globulins under paragraph (1)(E)(ii) and costs
19 incurred by physicians for furnishing these
20 products; and

21 “(ii) review available data, including survey
22 data presented by members of the IVIG com-
23 munity and pricing data collected by the Fed-
24 eral Government, on the access of individuals
25 eligible for services under this part to immune
26 globulins.

1 “(B) Upon completion of the review and collec-
2 tion of data under subparagraph (A), and not later
3 than 7 months after the date of the enactment of
4 this paragraph, the Secretary shall provide, if appro-
5 priate, to physicians furnishing immune globulins, a
6 payment, in addition to the payment provided for in
7 paragraph (1)(E)(ii), for all items related to the fur-
8 nishing of immune globulins, in an amount that the
9 Secretary determines to be appropriate. Such pay-
10 ment shall continue, subject to subparagraph (C),
11 for a period of 2 years beginning on the date such
12 additional payment is first provided under this sub-
13 paragraph.

14 “(C) The Secretary shall consider the rec-
15 ommendations made by the Medicare Payment Advi-
16 sory Commission made under section 6 of the Medi-
17 care Patient IVIG Access Act of 2009 and shall con-
18 sult with members of the IVIG community to deter-
19 mine whether the additional payment under sub-
20 paragraph (B) improved beneficiary access to intra-
21 venous immune globulins and, if so, the Secretary
22 may extend payment under such subparagraph be-
23 yond the 2-year period specified in such subpara-
24 graph. The Secretary shall submit to Congress a re-
25 port on the Secretary’s exercise (or non-exercise) of

1 authority under the previous sentence, including the
2 reasons for such exercise (or non-exercise).”.

3 (b) AS PART OF HOSPITAL OUTPATIENT SERV-
4 ICES.—Section 1833(t)(14) of such Act (42 U.S.C.
5 1395l(t)(14)) is amended—

6 (1) in subparagraph (A)(iii), by striking “sub-
7 paragraph (E)” and inserting “subparagraphs (E)
8 and (I)”; and

9 (2) by adding at the end the following new sub-
10 paragraph:

11 “(I) ADDITIONAL PAYMENT FOR IMMUNE
12 GLOBULINS.—

13 “(i) DATA COLLECTION AND RE-
14 VIEW.—Not later than 6 months after the
15 date of the enactment of the Medicare Pa-
16 tient IVIG Access Act of 2009, the Sec-
17 retary shall—

18 “(I) review available data, includ-
19 ing survey data presented by members
20 of the IVIG community and pricing
21 data collected by the Federal Govern-
22 ment, on the access of individuals eli-
23 gible for services under this part to
24 immune globulins; and

1 “(II) collect data on the dif-
2 ferences, if any, between payments for
3 immune globulins under subparagraph
4 (A)(iii) and costs incurred for fur-
5 nishing these products.

6 “(ii) ADDITIONAL PAYMENT AUTHOR-
7 ITY.—Upon completion of the review and
8 collection of data under clause (i), and not
9 later than 7 months after the date of the
10 enactment of this subparagraph, the Sec-
11 retary shall provide, if appropriate, to hos-
12 pitals furnishing immune globulins as part
13 of a covered OPD service, a payment, in
14 addition to the payment provided for under
15 subparagraph (A)(iii), for all items related
16 to the furnishing of immune globulins, in
17 an amount that the Secretary determines
18 to be appropriate. Such payment shall con-
19 tinue for a period of 2 years beginning on
20 the date such additional payment is first
21 provided under this clause. The Secretary
22 shall consider the recommendations made
23 by the Medicare Payment Advisory Com-
24 mission made under section 6 of the Medi-
25 care Patient IVIG Access Act of 2009 and

1 shall consult with members of the IVIG
2 community to determine whether the addi-
3 tional payment under the previous sentence
4 improved beneficiary access to intravenous
5 immune globulins and, if so, the Secretary
6 may extend payment under such sentence
7 beyond the 2-year period specified in such
8 sentence. The Secretary shall submit to
9 Congress a report on the exercise (or non-
10 exercise) of authority under the previous
11 sentence, including the reasons for such
12 exercise (or nonexercise).”.

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

15 (a) INCLUDING COVERAGE OF ADMINISTRATION.—
16 Section 1861 of the Social Security Act (42 U.S.C. 1395x)
17 is amended—

18 (1) in subsection (s)(2)(Z), by inserting “and
19 items and services related to the administration of
20 intravenous immune globulin” after “globulin”; and

21 (2) in subsection (zz), by striking “but not in-
22 cluding items or services related to the administra-
23 tion of the derivative,”.

24 (b) PAYMENT FOR INTRAVENOUS IMMUNE GLOBULIN
25 ADMINISTRATION IN THE HOME.—Section 1842(o) of

1 such Act (42 U.S.C. 1395u(o)), as amended by section
2 3(a), is amended—

3 (1) in paragraph (1)(E)(ii), by striking “para-
4 graph (7)” and inserting “paragraph (7) or (8)”;

5 (2) by redesignating paragraph (8) as para-
6 graph (9); and

7 (3) by inserting after paragraph (7) the fol-
8 lowing new paragraph:

9 “(8)(A) Subject to subparagraph (B), in the
10 case of intravenous immune globulins described in
11 section 1861(s)(2)(Z) that are furnished on or after
12 January 1, 2010, the Secretary shall provide for a
13 separate payment for items and services related to
14 the administration of such intravenous immune
15 globulins in an amount that the Secretary deter-
16 mines to be appropriate based on a review of avail-
17 able published and unpublished data and informa-
18 tion, including the Study of Intravenous Immune
19 Globulin Administration Options: Safety, Access,
20 and Cost Issues conducted by the Secretary (CMS
21 Contract #500–95–0059). Such payment amount
22 may take into account the following:

23 “(i) Pharmacy overhead and related ex-
24 penses.

25 “(ii) Patient service costs.

1 “(iii) Supply costs.

2 “(B) The separate payment amount provided
3 under this paragraph for intravenous immune
4 globulins furnished in 2010 or a subsequent year
5 shall be equal to the separate payment amount de-
6 termined under this paragraph for the previous year
7 increased by the percentage increase in the medical
8 care component of the consumer price index for all
9 urban consumers (United States city average) for
10 the 12-month period ending with June of the pre-
11 vious year.”.

12 (c) EFFECTIVE DATE.—The amendments made by
13 subsections (a) and (b) shall apply to intravenous immune
14 globulin administered on or after January 1, 2010.

15 **SEC. 5. COLLECTION OF DATA AND REVIEW OF COM-**
16 **PLEXITY CODES FOR PHYSICIAN ADMINIS-**
17 **TRATION OF IVIG.**

18 (a) DATA COLLECTION.—The Secretary of Health
19 and Human Services shall enter into a contract for the
20 collection of data if the Secretary determines, by not later
21 than 6 months after the date of the enactment of this Act,
22 that collection of additional data on the practice of IVIG
23 infusion, including collection of data on the complexity of
24 such infusions, are necessary.

1 (b) DATA REVIEW.—The Secretary shall review data
2 collected under such contract as well as data submitted
3 by members of the medical community related to the cur-
4 rent infusion payment codes under part B of title XVIII
5 of the Social Security Act.

6 (c) MODIFICATION OF CODES.—Upon completion of
7 any data collection under subsection (a) and the review
8 under subsection (b) and not later than 7 months after
9 the date of the enactment of this Act, the Secretary
10 shall—

11 (1) provide notice to the appropriate Medicare
12 administrative contractors regarding which existing
13 infusion codes shall be used for purposes of IVIG re-
14 imbursement under part B of title XVIII of the So-
15 cial Security Act; or

16 (2) submit to Congress and the RBRVS Update
17 Committee (RUC) a report on why an additional in-
18 fusion payment code is necessary.

19 **SEC. 6. REPORTS.**

20 (a) REPORT BY THE SECRETARY.—Not later than 7
21 months after the date of the enactment of this Act, the
22 Secretary of Health and Human Services shall submit a
23 report to Congress on the following:

24 (1) The results of the data collection and review
25 conducted by the Secretary under subparagraph (A)

1 of section 1842(o)(7) of the Social Security Act, as
2 added by section 3(a), and clause (i) of section
3 1833(t)(14)(I) of such Act, as added by section 3(b).

4 (2) Whether the Secretary plans to use the au-
5 thority under subparagraph (C) of such section
6 1842(o)(7) and clause (iii) of such section
7 1833(t)(14)(I) of such Act to provide an additional
8 payment to physicians furnishing intravenous im-
9 mune globulins and, if the Secretary does not plan
10 to use such authority, the reasons why the payment
11 is appropriate without such an additional payment
12 based on the data collected and reviewed.

13 (b) MEDPAC REPORT.—Not later than 2 years after
14 the date of the enactment of this Act, the Medicare Pay-
15 ment Advisory Commission shall submit a report to the
16 Secretary and to Congress that contains the following:

17 (1) In the case where the Secretary has used
18 the authority under sections 1842(o)(7)(C) and
19 1833(t)(14)(I)(iii) of the Social Security Act, as
20 added by subsections (a) and (b), respectively, of
21 section 3 to provide an additional payment to physi-
22 cians furnishing intravenous immune globulins dur-
23 ing the preceding year, an analysis of whether bene-
24 ficiary access to intravenous immune globulins under
25 the Medicare program under title XVIII of the So-

1 cial Security Act has improved as a result of the
2 Secretary's use of such authority.

3 (2) An analysis of the appropriateness of imple-
4 menting a new methodology for payment for intra-
5 venous immune globulins under part B of title
6 XVIII of the Social Security Act (42 U.S.C. 1395k
7 et seq.).

8 (3) An analysis of the feasibility of reducing the
9 lag time with respect to data used to determine aver-
10 age sales price under section 1847A of the Social
11 Security Act (42 U.S.C. 1395w-3a).

12 (4) Recommendations for such legislation and
13 administrative action as the Medicare Payment Ad-
14 visory Commission determines appropriate.

15 **SEC. 7. MEDICARE COVERAGE OF DISPOSABLE PUMPS AS**
16 **ITEMS OF DURABLE MEDICAL EQUIPMENT IN**
17 **CERTAIN CASES.**

18 (a) IN GENERAL.—Section 1861(n) of the Social Se-
19 curity Act (42 m 1395x(n)) is amended by inserting before
20 the semicolon the following: “and includes a disposable
21 pump prescribed, instead of a non-disposable external in-
22 fusion pump, for administration of a drug used as part
23 of a chemotherapy regimen for the treatment of colorectal
24 cancer if a non-disposable external infusion pump would

1 have been covered under this subsection to administer the
2 same drug for the same indication as of July 1, 2008”.

3 (b) **EFFECTIVE DATE.**—The amendment made by
4 subsection (a) shall apply to disposable pumps furnished
5 on or after January 1, 2010.

○