

111TH CONGRESS
1ST SESSION

S. 701

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

IN THE SENATE OF THE UNITED STATES

MARCH 25, 2009

Mr. KERRY (for himself, Mr. ALEXANDER, Mr. WYDEN, Mr. WHITEHOUSE, and Mr. BROWNBACK) introduced the following bill; which was read twice and referred to the Committee on Finance

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. Offset.

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.
22 The differences in basic fractionation and the addi-
23 tion of various modifications for further purification,

1 stabilization, and virus inactivation/removal yield
2 clearly different biological products. As a result,
3 IVIG therapies are not interchangeable, with patient
4 tolerance differing from one IVIG brand to another.

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

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

24 (6) An Office of the Inspector General (OIG)
25 April 2007 report, Intravenous Immune Globulin:

1 Medicare Payment and Availability, found that
2 Medicare reimbursement for IVIG was inadequate to
3 cover the cost many providers must pay for the
4 product. During the third quarter of 2006, 44 per-
5 cent of IVIG sales to hospitals and 41 percent of
6 sales to physicians by the three largest distributors
7 occurred at prices above Medicare payment amounts.

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

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

24 (9) The OIG's 2007 report concluded that
25 whatever improvement some providers saw in the re-

1 relationship of Medicare reimbursement for IVIG to
2 prices paid during the first three quarters of 2006
3 would be eroded if manufacturers were to increase
4 prices for IVIG in the future.

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

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

22 (12) The ASPE report, Analysis of Supply,
23 Distribution, Demand, and Access Issues Associated
24 with Immune Globulin Intravenous (IGIV), found
25 that Medicare's IVIG home infusion benefit is not

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

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

12 (B) not being reimbursed for the infusion
13 services provided by a nurse.

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

21 **SEC. 3. MEDICARE PAYMENT FOR INTRAVENOUS IMMUNE**
22 **GLOBULINS (IVIG).**

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

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

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

7 (3) by inserting after paragraph (6) the fol-
8 lowing new paragraph:

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

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

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

23 “(B) Upon completion of the review and collec-
24 tion of data under subparagraph (A), and not later
25 than 7 months after the date of the enactment of

1 this paragraph, the Secretary shall provide, if appro-
 2 priate, to physicians furnishing immune globulins, a
 3 payment, in addition to the payment provided for in
 4 paragraph (1)(E)(ii), for all items related to the fur-
 5 nishing of immune globulins, in an amount that the
 6 Secretary determines to be appropriate. Such pay-
 7 ment shall continue for a period of 2 years begin-
 8 ning on the date such additional payment is first
 9 provided under this subparagraph.”.

10 (b) AS PART OF HOSPITAL OUTPATIENT SERV-
 11 ICES.—Section 1833(t)(14) of such Act (42 U.S.C.
 12 1395l(t)(14)) is amended—

13 (1) in subparagraph (A)(iii), in the matter pre-
 14 ceding subclause (I), by striking “subparagraph
 15 (E)” and inserting “subparagraphs (E) and (I)”;
 16 and

17 (2) by adding at the end the following new sub-
 18 paragraph:

19 “(I) ADDITIONAL PAYMENT FOR IMMUNE
 20 GLOBULINS.—

21 “(i) DATA COLLECTION AND RE-
 22 VIEW.—Not later than 6 months after the
 23 date of the enactment of the Medicare Pa-
 24 tient IVIG Access Act of 2009, the Sec-
 25 retary shall—

1 “(I) review available data, includ-
2 ing survey data presented by members
3 of the IVIG community and pricing
4 data collected by the Federal Govern-
5 ment, on the access of individuals eli-
6 gible for services under this part to
7 immune globulins; and

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

13 “(ii) ADDITIONAL PAYMENT AUTHOR-
14 ITY.—Upon completion of the review and
15 collection of data under clause (i), and not
16 later than 7 months after the date of the
17 enactment of this subparagraph, 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 related
23 to the furnishing of immune globulins, in
24 an amount that the Secretary determines
25 to be appropriate. Such payment shall con-

1 tinue for a period of 2 years beginning on
 2 the date such additional payment is first
 3 provided under this clause.”.

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

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

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

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

15 (b) PAYMENT FOR INTRAVENOUS IMMUNE GLOBULIN
 16 ADMINISTRATION IN THE HOME.—Section 1842(o) of
 17 such Act (42 U.S.C. 1395u(o)), as amended by section
 18 3(a), is amended—

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

21 (2) by redesignating paragraph (8) as para-
 22 graph (9); and

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

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

15 “(i) Pharmacy overhead and related ex-
16 penses.

17 “(ii) Patient service costs.

18 “(iii) Supply costs.

19 “(B) The separate payment amount provided
20 under this paragraph for intravenous immune
21 globulins furnished in 2010 or a subsequent year
22 shall be equal to the separate payment amount de-
23 termined under this paragraph for the previous year
24 increased by the percentage increase in the medical
25 care component of the consumer price index for all

1 urban consumers (United States city average) for
2 the 12-month period ending with June of the pre-
3 vious year.”.

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

7 **SEC. 5. COLLECTION OF DATA AND REVIEW OF COM-**
8 **PLEXITY CODES FOR PHYSICIAN ADMINIS-**
9 **TRATION OF IVIG.**

10 (a) DATA COLLECTION.—The Secretary of Health
11 and Human Services may enter into a contract for the
12 collection of data, by not later than 6 months after the
13 date of the enactment of this Act, on the practice of IVIG
14 infusion, including collection of data on the complexity of
15 such infusions.

16 (b) DATA REVIEW.—Not later than 6 months after
17 the date of the enactment of this Act, the Secretary shall
18 review data collected under such contract as well as data
19 submitted by members of the medical community related
20 to the current infusion payment codes under part B of
21 title XVIII of the Social Security Act.

22 (c) MODIFICATION OF CODES.—Upon completion of
23 any data collection under subsection (a) and the review
24 under subsection (b) and not later than 7 months after

1 the date of the enactment of this Act, the Secretary
2 shall—

3 (1) provide notice to the appropriate Medicare
4 administrative contractors regarding which existing
5 infusion codes shall be used for purposes of IVIG re-
6 imbursement under part B of title XVIII of the So-
7 cial Security Act; or

8 (2) submit to Congress and the RBRUS Com-
9 mittee (RUC) a report on why an additional infusion
10 payment code is necessary.

11 **SEC. 6. REPORTS.**

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

16 (1) The results of the data collection and review
17 conducted by the Secretary under subparagraph (A)
18 of section 1842(o)(7) of the Social Security Act, as
19 added by section 3(a), and clause (i) of section
20 1833(t)(14)(I) of such Act, as added by section 3(b).

21 (2) Whether the Secretary plans to use the au-
22 thority under subparagraph (C) of such section
23 1842(o)(7) and clause (iii) of such section
24 1833(t)(14)(I) of such Act to provide an additional
25 payment to physicians furnishing intravenous im-

1 mune globulins and, if the Secretary does not plan
2 to use such authority, the reasons why the payment
3 is appropriate without such an additional payment
4 based on the data collected and reviewed.

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

9 (1) In the case where the Secretary has used
10 the authority under sections 1842(o)(7)(C) and
11 1833(t)(14)(I)(iii) of the Social Security Act, as
12 added by subsections (a) and (b), respectively, of
13 section 3 to provide an additional payment to physi-
14 cians furnishing intravenous immune globulins dur-
15 ing the preceding year, an analysis of whether bene-
16 ficiary access to intravenous immune globulins under
17 the Medicare program under title XVIII of the So-
18 cial Security Act has improved as a result of the
19 Secretary's use of such authority.

20 (2) An analysis of the appropriateness of imple-
21 menting a new methodology for payment for intra-
22 venous immune globulins under part B of title
23 XVIII of the Social Security Act (42 U.S.C. 1395k
24 et seq.).

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

5 (4) Recommendations for such legislation and
6 administrative action as the Medicare Payment Ad-
7 visory Commission determines appropriate.

8 **SEC. 7. OFFSET.**

9 Section 1861(n) of the Social Security Act (42 U.S.C.
10 1395x(n)) is amended by adding at the end the following:
11 “Such term includes disposable drug delivery systems, in-
12 cluding elastomeric infusion pumps, for the treatment of
13 colorectal cancer.”.

○