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

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A BILL

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

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Medicare Patient IVIG Access Act of 2009''.

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

SEC. 2. FINDINGS.

(a) FINDINGS.—Congress finds the following:

(1) The 2001 report of the Medicare Payment Advisory Commission to Congress states that ''to help ensure beneficiaries' access to high-quality care, Medicare payments should correspond to the cost efficient providers incur in furnishing this care''. Payments that do not meet this objective may create barriers to access.

(2) Intravenous immune globulin (IVIG) is a human blood plasma derived product, which over the past 25 years has become an invaluable therapy for many chronic conditions and illnesses, including primary immunodeficiency diseases, autoimmune, and neurological disorders. For many of these disorders, IVIG is the most effective and viable treatment available, and has dramatically improved the quality of life for persons with these conditions and has become a life-saving therapy for many.

(3) The Food and Drug Administration (FDA) recognizes each IVIG brand as a unique biologic. The differences in basic fractionation and the addition of various modifications for further purification,

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

(4) The report of the Office of the Assistant Secretary for Planning and Evaluation (ASPE), Department of Health and Human Services (DHHS), ''Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)'', issued in May 2007, found that IVIG manufacturing is complex and requires substantial upfront cash outlay and planning and takes between 7 and 12 months from plasma collection at donor centers to FDA lot release.

(5) The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 changed Medicare's reimbursement methodology for IVIG from average wholesale price (AWP) to average sales price plus 6 percent (ASP+6), effective January 1, 2005, for physicians, and January 1, 2006, for hospital outpatient departments, thereby reducing reimbursement rates paid to these providers of IVIG on behalf of Medicare beneficiaries.

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

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

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

(8) The OIG also reported that 61 percent of responding physicians indicated that they had sent patients to hospitals for IVIG treatment, largely because of their inability to purchase IVIG at prices below the Medicare payment amounts. In addition, OIG found that some physicians had stopped providing IVIG to Medicare beneficiaries altogether.

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

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

(10) The Centers for Medicare & Medicaid Services, in recognition of dislocations experienced by patients and providers in obtaining IVIG since the change to the ASP+6 reimbursement methodology, has provided during 2006 and 2007 a temporary additional payment for IVIG preadministration-related services to compensate physicians and hospital outpatient departments for the extra resources they have had to expend in locating and obtaining appropriate IVIG products and in scheduling patient infusions.

(11) The Medicare Modernization Act of 2003 (MMA) established an IVIG home infusion benefit for persons with primary immunodeficiency disease (PIDD), paying only for IVIG and specifically excluding coverage of items and services related to administration of the product.

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

designed to reimburse for more than the cost of IVIG and does not cover the cost of infusion services (for example, nursing and clinical services and supplies) in the home. As a consequence, the report found that home infusion providers generally do not accept new PIDD patients with only Medicare coverage. These limitations in service are caused by health care providers—

(A) not being able to acquire IVIG at prices at or below the Medicare part B reimbursement level; and

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

(13) Physicians administering IVIG to Medicare beneficiaries are reimbursed at the same low complexity level as the administration of antibiotics. However the administration of IVIG requires special preparation and handling, involves significant patient risk, and prolonged nursing time to monitor the patient during infusion.

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

(a) IN GENERAL.—Section 1842(o) of the Social Security Act (42 U.S.C. 1395u(o)) is amended—

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

(2) in paragraph (7), by striking "(6)" and inserting "(7)" and by redesignating it as paragraph (8); and

(3) by inserting after paragraph (6) the following new paragraph:

"(7)(A) Not later than 6 months after the date of the enactment of the Medicare Patient IVIG Access Act of 2009, the Secretary shall—

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

"(ii) review available data, including survey data presented by members of the IVIG community and pricing data collected by the Federal Government, on the access of individuals eligible for services under this part to immune globulins.

"(B) Upon completion of the review and collection of data under subparagraph (A), and not later than 7 months after the date of the enactment of

this paragraph, the Secretary shall provide, if appropriate, to physicians furnishing immune globulins, a payment, in addition to the payment provided for in paragraph (1)(E)(ii), for all items related to the furnishing of immune globulins, in an amount that the Secretary determines to be appropriate. Such payment shall continue for a period of 2 years beginning on the date such additional payment is first provided under this subparagraph.''.

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

(1) in subparagraph (A)(iii), in the matter preceding subclause (I), by striking ''subparagraph (E)'' and inserting ''subparagraphs (E) and (I)''; and

(2) by adding at the end the following new subparagraph:

''(I) ADDITIONAL PAYMENT FOR IMMUNE GLOBULINS.—

''(i) DATA COLLECTION AND REVIEW.—Not later than 6 months after the date of the enactment of the Medicare Patient IVIG Access Act of 2009, the Secretary shall—

''(I) review available data, including survey data presented by members of the IVIG community and pricing data collected by the Federal Government, on the access of individuals eligible for services under this part to immune globulins; and

''(II) collect data on the differences, if any, between payments for immune globulins under subparagraph (A)(iii) and costs incurred for furnishing these products.

''(ii) ADDITIONAL PAYMENT AUTHORITY.—Upon completion of the review and collection of data under clause (i), and not later than 7 months after the date of the enactment of this subparagraph, the Secretary shall provide, if appropriate, to hospitals furnishing immune globulins as part of a covered OPD service, a payment, in addition to the payment provided for under subparagraph (A)(iii), for all items related to the furnishing of immune globulins, in an amount that the Secretary determines to be appropriate. Such payment shall con-

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

SEC. 4. COVERAGE AND PAYMENT OF INTRAVENOUS IMMUNE GLOBULIN IN THE HOME.

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

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

(2) in subsection (zz), by striking ''but not including items or services related to the administration of the derivative,''.

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

(1) in paragraph (1)(E)(ii), by striking ''paragraph (7)'' and inserting ''paragraph (7) or (8)'';

(2) by redesignating paragraph (8) as paragraph (9); and

(3) by inserting after paragraph (7) the following new paragraph:

''(8)(A) Subject to subparagraph (B), in the case of intravenous immune globulins described in section 1861(s)(2)(Z) that are furnished on or after January 1, 2010, the Secretary shall provide for a separate payment for items and services related to the administration of such intravenous immune globulins in an amount that the Secretary determines to be appropriate based on a review of available published and unpublished data and information, including the Study of Intravenous Immune Globulin Administration Options: Safety, Access, and Cost Issues conducted by the Secretary (CMS Contract #500–95–0059). Such payment amount may take into account the following:

''(i) Pharmacy overhead and related expenses.

''(ii) Patient service costs.

''(iii) Supply costs.

''(B) The separate payment amount provided under this paragraph for intravenous immune globulins furnished in 2010 or a subsequent year shall be equal to the separate payment amount determined under this paragraph for the previous year increased by the percentage increase in the medical care component of the consumer price index for all

urban consumers (United States city average) for the 12-month period ending with June of the previous year.''.

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

SEC. 5. COLLECTION OF DATA AND REVIEW OF COMPLEXITY CODES FOR PHYSICIAN ADMINISTRATION OF IVIG.

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

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

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

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

(1) provide notice to the appropriate Medicare administrative contractors regarding which existing infusion codes shall be used for purposes of IVIG reimbursement under part B of title XVIII of the Social Security Act; or

(2) submit to Congress and the RBRUS Committee (RUC) a report on why an additional infusion payment code is necessary.

SEC. 6. REPORTS.

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

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

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

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

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

(1) In the case where the Secretary has used the authority under sections 1842(o)(7)(C) and 1833(t)(14)(I)(iii) of the Social Security Act, as added by subsections (a) and (b), respectively, of section 3 to provide an additional payment to physicians furnishing intravenous immune globulins during the preceding year, an analysis of whether beneficiary access to intravenous immune globulins under the Medicare program under title XVIII of the Social Security Act has improved as a result of the Secretary's use of such authority.

(2) An analysis of the appropriateness of implementing a new methodology for payment for intravenous immune globulins under part B of title XVIII of the Social Security Act (42 U.S.C. 1395k et seq.).

(3) An analysis of the feasibility 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).

(4) Recommendations for such legislation and administrative action as the Medicare Payment Advisory Commission determines appropriate.

SEC. 7. OFFSET.

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.''.

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