110TH CONGRESS
2D SESSION

S. 2990

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

IN THE SENATE OF THE UNITED STATES

MAY 7, 2008

Mr. KERRY (for himself, Mr. ALEXANDER, and Ms. STABENOW) 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.

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 IVIG Access Act of 2008''.

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

SEC. 2. FINDINGS.

Congress makes the following findings:

(1) Intravenous immune globulin (IVIG) is a human blood plasma derived product, which over the past 25 years has become an invaluable therapy for many primary immunodeficiency diseases, as well as a number of neurological, autoimmune, and other chronic conditions and illnesses. 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.

(2) The Food and Drug Administration 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.

(3) The report of the Office of the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services, ''Analysis of Supply, Distribution, Demand, and Access Issues

Associated with Immune Globulin Intravenous (IGIV)'', that was issued in May 2007, found that IVIG manufacturing is complex and requires substantial up-front cash outlay and planning and takes between 7 and 12 months from plasma collection at donor centers to lot release by the Food and Drug Administration.

(4) The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2066) changed Medicare's reimbursement methodology for IVIG from average wholesale price (AWP) to average sales price plus 6 percent (ASP+6 percent), effective January 1, 2005, for physicians, and January 1, 2006, for hospital outpatient departments, thereby reducing reimbursement rates paid to those providers of IVIG on behalf of Medicare beneficiaries.

(5) An April 2007 report of the Office of Inspector General of the Department of Health and Human Services, ''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 3 largest distributors occurred at prices above Medicare payment amounts.

(6) The report of the Office of the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services, ''Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)'' 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 a lack of continuity of care and has had an adverse impact on health outcomes and quality of life.

(7) The Office of Inspector General of the Department of Health and Human Services 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, the Office of Inspector General found that some physicians had stopped providing IVIG to Medicare beneficiaries altogether.

(8) The Office of Inspector General's 2007 report concluded that whatever improvement some providers saw in the relationship of Medicare reimbursement for IVIG to prices paid during the first 3 quarters of 2006 would be eroded if manufacturers were to increase prices for IVIG in the future.

(9) 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 a temporary additional payment during 2006 and 2007 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.

(10) Approximately 10,000 Medicare beneficiaries receive IVIG treatment for their primary immunodeficiency disease in a variety of different settings. Those beneficiaries have no other effective treatment for their condition.

(11) The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established an IVIG home infusion benefit for persons with primary

immune deficiency disease, paying only for IVIG and specifically excluding coverage of items and services related to administration of the product.

(12) The report of the Office of the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services, ''Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)'', noted that, because of limitations in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 provision, Medicare's IVIG home infusion benefit is not designed to provide reimbursement for more than the cost of IVIG and does not cover the cost of infusion services (such as nursing and clinical services and supplies) in the home. As a consequence, the report found that home infusion providers generally do not accept new patients who have primary immune deficiency disease and only have 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) Access to home infusion of IVIG for patients with primary immune deficiency disease, who have a genetic or intrinsic defect in their human immune system, will reduce their exposure to infections at a time when their antibodies are compromised and will improve the quality of care and health of the patient.

SEC. 3. MEDICARE PAYMENT FOR INTRAVENOUS IMMUNE GLOBULINS.

(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 ", plus an additional amount (if applicable) under paragraph (7)" before the period at the end;

(2) by redesignating paragraph (7) 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 enactment of the Medicare IVIG Access Act of 2008, the Secretary shall—

"(i) collect data on the differences, if any, between payments to physicians for intravenous immune globulin under paragraph (1)(E)(ii)

and costs incurred by physicians for furnishing such products; and

''(ii) review available data, including survey and pricing data collected by the Federal Government and data presented by members of the intravenous immune globulin community on the access of individuals eligible for services under this part to intravenous immune globulin and the differences described in clause (i).

''(B) Subject to subparagraph (C), in the case of intravenous immune globulin furnished on or after the date of enactment of this paragraph, the Secretary shall continue the IVIG preadministration-related services payment established under the final rule promulgated by the Secretary in the Federal Register on November 27, 2007 (72 Fed. Reg. 66254), until such time as the Secretary determines that payment for intravenous immune globulin is adequate.

''(C) Upon collection of data and completion of the review under subparagraph (A), the Secretary shall, during a 2-year period beginning not later than 7 months after such date of enactment, provide, if appropriate, to physicians furnishing intravenous immune globulins, a payment, in addition to

the payment under paragraph (1)(E)(ii) and instead of the IVIG preadministration-related services payment under subparagraph (B), for all items related to the furnishing of intravenous immune globulin, in an amount the Secretary determines to be appropriate.''.

(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), 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 INTRAVENOUS IMMUNE GLOBULIN.—

''(i) DATA COLLECTION AND REVIEW.—Not later than 6 months after the date of enactment of the Medicare IVIG Access Act of 2008, the Secretary shall—

''(I) collect data on the differences, if any, between payments of intravenous immune globulin under subparagraph (A)(iii) and costs in-

curred by a hospital for furnishing such products; and

''(II) review available data, including survey and pricing data collected by the Federal Government and data presented by members of the intravenous immune globulin community on the access of individuals eligible for services under this part to intravenous immune globulin and the differences described in subclause (I).

''(ii) CONTINUATION OF SPECIAL PAYMENT RULE.—Subject to clause (iii), in the case of intravenous immune globulin furnished on or after the date of enactment of this subparagraph, the Secretary shall continue the IVIG preadministration-related services payment established under the final rule promulgated by the Secretary in the Federal Register on November 27, 2007 (72 Fed. Reg. 66697), until such time as the Secretary determines that payment for intravenous immune globulin is adequate.

''(iii) ADDITIONAL PAYMENT AUTHORITY.—Upon collection of data and completion of the review under clause (i), the Secretary shall, during a 2-year period beginning not later than 7 months after such date of enactment, provide, if appropriate, to hospitals furnishing intravenous immune globulin as part of a covered OPD service, in addition to the payment under subparagraph (A)(iii) and instead of the IVIG preadministration-related services payment under clause (ii), for all items related to the furnishing of intravenous immune globulin, in an amount the Secretary determines to be appropriate.''.

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

(a) IN GENERAL.—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 the Social Security Act (42 U.S.C. 1395u(o), as amended by section 3), 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, 2008, 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 2009 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.''.

SEC. 5. REPORTS.

(a) REPORT BY THE SECRETARY.—Not later than 7 months after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') 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) to provide an additional payment to physicians furnishing intravenous immune globulins.

(b) MEDPAC REPORT.—Not later than 2 years after the date of 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 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, including recommendations for such legislation and administrative action as the Commission determines is necessary to implement any methodology analyzed under paragraph (2).

SEC. 6. 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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