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H. R. 1845

One Hundred Twelfth Congress of the United States of America

AT THE SECOND SESSION

Begun and held at the City of Washington on Tuesday, the third day of January, two thousand and twelve

An Act

To provide a demonstration project providing Medicare coverage for in-home administration of intravenous immune globulin (IVIG) and to amend title XVIII of the Social Security Act with respect to the application of Medicare secondary payer rules for certain claims.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the "Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012".

TITLE I—MEDICARE IVIG ACCESS

SEC. 101. MEDICARE PATIENT IVIG ACCESS DEMONSTRATION PROJECT.

(a) ESTABLISHMENT.—The Secretary shall establish and implement a demonstration project under part B of title XVIII of the Social Security Act to evaluate the benefits of providing payment for items and services needed for the in-home administration of intravenous immune globin for the treatment of primary immune deficiency diseases.

(b) DURATION AND SCOPE.—

(1) DURATION.—Beginning not later than one year after the date of enactment of this Act, the Secretary shall conduct the demonstration project for a period of 3 years.

(2) SCOPE.—The Secretary shall enroll not more than 4,000 Medicare beneficiaries who have been diagnosed with primary immunodeficiency disease for participation in the demonstration project. A Medicare beneficiary may participate in the demonstration project on a voluntary basis and may terminate participation at any time.

(c) COVERAGE.—Except as otherwise provided in this section, items and services for which payment may be made under the demonstration program shall be treated and covered under part B of title XVIII of the Social Security Act in the same manner as similar items and services covered under such part.

(d) PAYMENT.—The Secretary shall establish a per visit payment amount for items and services needed for the in-home administration of intravenous immune globin based on the national per visit low-utilization payment amount under the prospective payment system for home health services established under section 1895 of the Social Security Act (42 U.S.C. 1395fff).

(e) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII of the Social Security Act as may be necessary to carry out the demonstration project.

(f) STUDY AND REPORT TO CONGRESS.—

(1) INTERIM EVALUATION AND REPORT.—Not later than three years after the date of enactment of this Act, the Secretary shall submit to Congress a report that contains an interim evaluation of the impact of the demonstration project on access for Medicare beneficiaries to items and services needed for the in-home administration of intravenous immune globin.

(2) FINAL EVALUATION AND REPORT.—Not later than one year after the date of completion of the demonstration project, the Secretary shall submit to Congress a report that contains the following:

(A) A final evaluation of the impact of the demonstration project on access for Medicare beneficiaries to items and services needed for the in-home administration of intravenous immune globin.

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

(C) An update to the report entitled "Analysis of Supply, Distribution, Demand, and Access Issues Associated with Immune Globulin Intravenous (IGIV)", issued in February 2007 by the Office of the Assistant Secretary for Planning and Evaluation of the Department of Health and Human Services.

(g) FUNDING.—There shall be made available to the Secretary to carry out the demonstration project not more than $45,000,000 from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t).

(h) DEFINITIONS.—In this section:

(1) DEMONSTRATION PROJECT.—The term "demonstration project" means the demonstration project conducted under this section.

(2) MEDICARE BENEFICIARY.—The term "Medicare beneficiary" means an individual who is enrolled for benefits under part B of title XVIII of the Social Security Act.

(3) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

TITLE II—STRENGTHENING MEDICARE SECONDARY PAYER RULES

SEC. 201. DETERMINATION OF REIMBURSEMENT AMOUNT THROUGH CMS WEBSITE TO IMPROVE PROGRAM EFFICIENCY.

Section 1862(b)(2)(B) of the Social Security Act (42 U.S.C. 1395y(b)(2)(B)) is amended by adding at the end the following new clause:

"(vii) USE OF WEBSITE TO DETERMINE FINAL CONDITIONAL REIMBURSEMENT AMOUNT.—

"(I) NOTICE TO SECRETARY OF EXPECTED DATE OF A SETTLEMENT, JUDGMENT, ETC.—In the case of a payment made by the Secretary pursuant to clause (i) for items and services provided to

the claimant, the claimant or applicable plan (as defined in paragraph (8)(F)) may at any time beginning 120 days before the reasonably expected date of a settlement, judgment, award, or other payment, notify the Secretary that a payment is reasonably expected and the expected date of such payment.

"(II) SECRETARIAL PROVIDING ACCESS TO CLAIMS INFORMATION THROUGH A WEBSITE.—The Secretary shall maintain and make available to individuals to whom items and services are furnished under this title (and to authorized family or other representatives recognized under regulations and to an applicable plan which has obtained the consent of the individual) access to information on the claims for such items and services (including payment amounts for such claims), including those claims that relate to a potential settlement, judgment, award, or other payment. Such access shall be provided to an individual, representative, or plan through a website that requires a password to gain access to the information. The Secretary shall update the information on claims and payments on such website in as timely a manner as possible but not later than 15 days after the date that payment is made. Information related to claims and payments subject to the notice under subclause (I) shall be maintained and made available consistent with the following:

"(aa) The information shall be as complete as possible and shall include provider or supplier name, diagnosis codes (if any), dates of service, and conditional payment amounts.

"(bb) The information accurately identifies those claims and payments that are related to a potential settlement, judgment, award, or other payment to which the provisions of this subsection apply.

"(cc) The website provides a method for the receipt of secure electronic communications with the individual, representative, or plan involved.

"(dd) The website provides that information is transmitted from the website in a form that includes an official time and date that the information is transmitted.

"(ee) The website shall permit the individual, representative, or plan to download a statement of reimbursement amounts (in this clause referred to as a 'statement of reimbursement amount') on payments for claims under this title relating to a potential settlement, judgment, award, or other payment.

"(III) USE OF TIMELY WEB DOWNLOAD AS BASIS FOR FINAL CONDITIONAL AMOUNT.—If an individual

(or other claimant or applicable plan with the consent of the individual) obtains a statement of reimbursement amount from the website during the protected period as defined in subclause (V) and the related settlement, judgment, award or other payment is made during such period, then the last statement of reimbursement amount that is downloaded during such period and within 3 business days before the date of the settlement, judgment, award, or other payment shall constitute the final conditional amount subject to recovery under clause (ii) related to such settlement, judgment, award, or other payment.

"(IV) RESOLUTION OF DISCREPANCIES.—If the individual (or authorized representative) believes there is a discrepancy with the statement of reimbursement amount, the Secretary shall provide a timely process to resolve the discrepancy. Under such process the individual (or representative) must provide documentation explaining the discrepancy and a proposal to resolve such discrepancy. Within 11 business days after the date of receipt of such documentation, the Secretary shall determine whether there is a reasonable basis to include or remove claims on the statement of reimbursement. If the Secretary does not make such determination within the 11 business-day period, then the proposal to resolve the discrepancy shall be accepted. If the Secretary determines within such period that there is not a reasonable basis to include or remove claims on the statement of reimbursement, the proposal shall be rejected. If the Secretary determines within such period that there is a reasonable basis to conclude there is a discrepancy, the Secretary must respond in a timely manner by agreeing to the proposal to resolve the discrepancy or by providing documentation showing with good cause why the Secretary is not agreeing to such proposal and establishing an alternate discrepancy resolution. In no case shall the process under this subclause be treated as an appeals process or as establishing a right of appeal for a statement of reimbursement amount and there shall be no administrative or judicial review of the Secretary's determinations under this subclause.

"(V) PROTECTED PERIOD.—In subclause (III), the term 'protected period' means, with respect to a settlement, judgment, award or other payment relating to an injury or incident, the portion (if any) of the period beginning on the date of notice under subclause (I) with respect to such settlement, judgment, award, or other payment that is after the end of a Secretarial response period beginning on the date of such notice to the Secretary. Such Secretarial response period shall be a period of 65 days, except that such period may

be extended by the Secretary for a period of an additional 30 days if the Secretary determines that additional time is required to address claims for which payment has been made. Such Secretarial response period shall be extended and shall not include any days for any part of which the Secretary determines (in accordance with regulations) that there was a failure in the claims and payment posting system and the failure was justified due to exceptional circumstances (as defined in such regulations). Such regulations shall define exceptional circumstances in a manner so that not more than 1 percent of the repayment obligations under this subclause would qualify as exceptional circumstances.

"(VI) EFFECTIVE DATE.—The Secretary shall promulgate final regulations to carry out this clause not later than 9 months after the date of the enactment of this clause.

"(VII) WEBSITE INCLUDING SUCCESSOR TECHNOLOGY.—In this clause, the term 'website' includes any successor technology.

"(viii) RIGHT OF APPEAL FOR SECONDARY PAYER DETERMINATIONS RELATING TO LIABILITY INSURANCE (INCLUDING SELF-INSURANCE), NO FAULT INSURANCE, AND WORKERS' COMPENSATION LAWS AND PLANS.—The Secretary shall promulgate regulations establishing a right of appeal and appeals process, with respect to any determination under this subsection for a payment made under this title for an item or service for which the Secretary is seeking to recover conditional payments from an applicable plan (as defined in paragraph (8)(F)) that is a primary plan under subsection (A)(ii), under which the applicable plan involved, or an attorney, agent, or third party administrator on behalf of such plan, may appeal such determination. The individual furnished such an item or service shall be notified of the plan's intent to appeal such determination".

SEC. 202. FISCAL EFFICIENCY AND REVENUE NEUTRALITY.

(a) IN GENERAL.—Section 1862(b) of the Social Security Act (42 U.S.C. 1395y(b)) is amended—

(1) in paragraph (2)(B)(ii), by striking "A primary plan" and inserting "Subject to paragraph (9), a primary plan"; and

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

"(9) EXCEPTION.—

"(A) IN GENERAL.—Clause (ii) of paragraph (2)(B) and any reporting required by paragraph (8) shall not apply with respect to any settlement, judgment, award, or other payment by an applicable plan arising from liability insurance (including self-insurance) and from alleged physical trauma-based incidents (excluding alleged ingestion, implantation, or exposure cases) constituting a total payment obligation to a claimant of not more than the single threshold amount calculated by the Secretary under subparagraph (B) for the year involved.

"(B) ANNUAL COMPUTATION OF THRESHOLD.—

"(i) IN GENERAL.—Not later than November 15 before each year, the Secretary shall calculate and publish a single threshold amount for settlements, judgments, awards, or other payments for obligations arising from liability insurance (including self-insurance) and for alleged physical trauma-based incidents (excluding alleged ingestion, implantation, or exposure cases) subject to this section for that year. The annual single threshold amount for a year shall be set such that the estimated average amount to be credited to the Medicare trust funds of collections of conditional payments from such settlements, judgments, awards, or other payments arising from liability insurance (including self-insurance) and for such alleged incidents subject to this section shall equal the estimated cost of collection incurred by the United States (including payments made to contractors) for a conditional payment arising from liability insurance (including self-insurance) and for such alleged incidents subject to this section for the year. At the time of calculating, but before publishing, the single threshold amount for a year, the Secretary shall inform, and seek review of, the Comptroller General of the United States with regard to such amount.

"(ii) PUBLICATION.—The Secretary shall include, as part of such publication for a year—

"(I) the estimated cost of collection incurred by the United States (including payments made to contractors) for a conditional payment arising from liability insurance (including self-insurance) and for such alleged incidents; and

"(II) a summary of the methodology and data used by the Secretary in computing such threshold amount and such cost of collection.

"(C) EXCLUSION OF ONGOING EXPENSES.—For purposes of this paragraph and with respect to a settlement, judgment, award, or other payment not otherwise addressed in clause (ii) of paragraph (2)(B) that includes ongoing responsibility for medical payments (excluding settlements, judgments, awards, or other payments made by a workers' compensation law or plan or no fault insurance), the amount utilized for calculation of the threshold described in subparagraph (A) shall include only the cumulative value of the medical payments made under this title.

"(D) REPORT TO CONGRESS.—Not later than November 15 before each year, the Secretary shall submit to the Congress a report on the single threshold amount for settlements, judgments, awards, or other payments for conditional payment obligations arising from liability insurance (including self-insurance) and alleged incidents described in subparagraph (A) for that year and on the establishment and application of similar thresholds for such payments for conditional payment obligations arising from worker compensation cases and from no fault insurance cases subject to this section for the year. For each such report, the Secretary shall—

"(i) calculate the threshold amount by using the methodology applicable to certain liability claims described in subparagraph (B); and

"(ii) include a summary of the methodology and data used in calculating each threshold amount and the amount of estimated savings under this title achieved by the Secretary implementing each such threshold.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to years beginning with 2014.

SEC. 203. REPORTING REQUIREMENT.

Section 1862(b)(8) of the Social Security Act (42 U.S.C. 1395y(b)(8)) is amended—

(1) in the first sentence of subparagraph (E)(i), by striking "shall be subject" and all that follows through the end of the sentence and inserting the following: "may be subject to a civil money penalty of up to $1,000 for each day of noncompliance with respect to each claimant."; and

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

"(I) REGULATIONS.—Not later than 60 days after the date of the enactment of this subparagraph, the Secretary shall publish a notice in the Federal Register soliciting proposals, which will be accepted during a 60-day period, for the specification of practices for which sanctions will and will not be imposed under subparagraph (E), including not imposing sanctions for good faith efforts to identify a beneficiary pursuant to this paragraph under an applicable entity responsible for reporting information. After considering the proposals so submitted, the Secretary, in consultation with the Attorney General, shall publish in the Federal Register, including a 60-day period for comment, proposed specified practices for which such sanctions will and will not be imposed. After considering any public comments received during such period, the Secretary shall issue final rules specifying such practices.".

SEC. 204. USE OF SOCIAL SECURITY NUMBERS AND OTHER IDENTIFYING INFORMATION IN REPORTING.

Section 1862(b)(8)(B) of the Social Security Act (42 U.S.C. 1395y(b)(8)(B)) is amended by adding at the end (after and below clause (ii)) the following:

"Not later than 18 months after the date of enactment of this sentence, the Secretary shall modify the reporting requirements under this paragraph so that an applicable plan in complying with such requirements is permitted but not required to access or report to the Secretary beneficiary social security account numbers or health identification claim numbers, except that the deadline for such modification shall be extended by one or more periods (specified by the Secretary) of up to 1 year each if the Secretary notifies the committees of jurisdiction of the House of Representatives and of the Senate that the prior deadline for such modification, without such extension, threatens patient privacy or the integrity of the secondary payer program under this subsection. Any such deadline extension notice shall include information on the progress being

made in implementing such modification and the anticipated implementation date for such modification.".

SEC. 205. STATUTE OF LIMITATIONS.

(a) IN GENERAL.—Section 1862(b)(2)(B)(iii) of the Social Security Act (42 U.S.C. 1395y(b)(2)(B)(iii)) is amended by adding at the end the following new sentence: "An action may not be brought by the United States under this clause with respect to payment owed unless the complaint is filed not later than 3 years after the date of the receipt of notice of a settlement, judgment, award, or other payment made pursuant to paragraph (8) relating to such payment owed.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply with respect to actions brought and penalties sought on or after 6 months after the date of the enactment of this Act.

Speaker of the House of Representatives.

Vice President of the United States and President of the Senate.