

112<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 1845

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IN THE SENATE OF THE UNITED STATES

DECEMBER 20, 2012

Received

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## 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.

1        *Be it enacted by the Senate and House of Representa-*  
2        *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Medicare IVIG Access  
3 and Strengthening Medicare and Repaying Taxpayers Act  
4 of 2012”.

5 **TITLE I—MEDICARE IVIG**  
6 **ACCESS**

7 **SEC. 101. MEDICARE PATIENT IVIG ACCESS DEMONSTRATION PROJECT.**  
8

9 (a) ESTABLISHMENT.—The Secretary shall establish  
10 and implement a demonstration project under part B of  
11 title XVIII of the Social Security Act to evaluate the bene-  
12 fits of providing payment for items and services needed  
13 for the in-home administration of intravenous immune  
14 globin for the treatment of primary immune deficiency dis-  
15 eases.

16 (b) DURATION AND SCOPE.—

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

21 (2) SCOPE.—The Secretary shall enroll not  
22 more than 4,000 Medicare beneficiaries who have  
23 been diagnosed with primary immunodeficiency dis-  
24 ease for participation in the demonstration project.

25 A Medicare beneficiary may participate in the dem-

1        onstration project on a voluntary basis and may ter-  
2        minate participation at any time.

3        (c) COVERAGE.—Except as otherwise provided in this  
4        section, items and services for which payment may be  
5        made under the demonstration program shall be treated  
6        and covered under part B of title XVIII of the Social Se-  
7        curity Act in the same manner as similar items and serv-  
8        ices covered under such part.

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

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

20       (f) STUDY AND REPORT TO CONGRESS.—

21                (1) INTERIM EVALUATION AND REPORT.—Not  
22       later than three years after the date of enactment of  
23       this Act, the Secretary shall submit to Congress a  
24       report that contains an interim evaluation of the im-  
25       pact of the demonstration project on access for

1 Medicare beneficiaries to items and services needed  
2 for the in-home administration of intravenous im-  
3 mune globin.

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

8 (A) A final evaluation of the impact of the  
9 demonstration project on access for Medicare  
10 beneficiaries to items and services needed for  
11 the in-home administration of intravenous im-  
12 mune globin.

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

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

1 (g) FUNDING.—There shall be made available to the  
2 Secretary to carry out the demonstration project not more  
3 than \$45,000,000 from the Federal Supplementary Med-  
4 ical Insurance Trust Fund under section 1841 of the So-  
5 cial Security Act (42 U.S.C. 1395t).

6 (h) DEFINITIONS.—In this section:

7 (1) DEMONSTRATION PROJECT.—The term  
8 “demonstration project” means the demonstration  
9 project conducted under this section.

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

14 (3) SECRETARY.—The term “Secretary” means  
15 the Secretary of Health and Human Services.

16 **TITLE II—STRENGTHENING**  
17 **MEDICARE SECONDARY**  
18 **PAYER RULES**

19 **SEC. 201. DETERMINATION OF REIMBURSEMENT AMOUNT**  
20 **THROUGH CMS WEBSITE TO IMPROVE PRO-**  
21 **GRAM EFFICIENCY.**

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

1           “(vii) USE OF WEBSITE TO DETER-  
2 MINE FINAL CONDITIONAL REIMBURSE-  
3 MENT AMOUNT.—

4           “(I) NOTICE TO SECRETARY OF  
5 EXPECTED DATE OF A SETTLEMENT,  
6 JUDGMENT, ETC.—In the case of a  
7 payment made by the Secretary pur-  
8 suant to clause (i) for items and serv-  
9 ices provided to the claimant, the  
10 claimant or applicable plan (as de-  
11 fined in paragraph (8)(F)) may at  
12 any time beginning 120 days before  
13 the reasonably expected date of a set-  
14 tlement, judgment, award, or other  
15 payment, notify the Secretary that a  
16 payment is reasonably expected and  
17 the expected date of such payment.

18           “(II) SECRETARIAL PROVIDING  
19 ACCESS TO CLAIMS INFORMATION  
20 THROUGH A WEBSITE.—The Sec-  
21 retary shall maintain and make avail-  
22 able to individuals to whom items and  
23 services are furnished under this title  
24 (and to authorized family or other  
25 representatives recognized under regu-

1                   lations and to an applicable plan  
2                   which has obtained the consent of the  
3                   individual) access to information on  
4                   the claims for such items and services  
5                   (including payment amounts for such  
6                   claims), including those claims that  
7                   relate to a potential settlement, judg-  
8                   ment, award, or other payment . Such  
9                   access shall be provided to an indi-  
10                  vidual, representative, or plan through  
11                  a website that requires a password to  
12                  gain access to the information. The  
13                  Secretary shall update the information  
14                  on claims and payments on such  
15                  website in as timely a manner as pos-  
16                  sible but not later than 15 days after  
17                  the date that payment is made. Infor-  
18                  mation related to claims and pay-  
19                  ments subject to the notice under sub-  
20                  clause (I) shall be maintained and  
21                  made available consistent with the fol-  
22                  lowing:

23                                   “(aa) The information shall  
24                                   be as complete as possible and  
25                                   shall include provider or supplier

1 name, diagnosis codes (if any),  
2 dates of service, and conditional  
3 payment amounts.

4 “(bb) The information accu-  
5 rately identifies those claims and  
6 payments that are related to a  
7 potential settlement, judgment,  
8 award, or other payment to  
9 which the provisions of this sub-  
10 section apply.

11 “(cc) The website provides a  
12 method for the receipt of secure  
13 electronic communications with  
14 the individual, representative, or  
15 plan involved.

16 “(dd) The website provides  
17 that information is transmitted  
18 from the website in a form that  
19 includes an official time and date  
20 that the information is trans-  
21 mitted.

22 “(ee) The website shall per-  
23 mit the individual, representative,  
24 or plan to download a statement  
25 of reimbursement amounts (in

1 this clause referred to as a ‘state-  
2 ment of reimbursement amount’)  
3 on payments for claims under  
4 this title relating to a potential  
5 settlement, judgment, award, or  
6 other payment.

7 “(III) USE OF TIMELY WEB  
8 DOWNLOAD AS BASIS FOR FINAL CON-  
9 DITIONAL AMOUNT.—If an individual  
10 (or other claimant or applicable plan  
11 with the consent of the individual) ob-  
12 tains a statement of reimbursement  
13 amount from the website during the  
14 protected period as defined in sub-  
15 clause (V) and the related settlement,  
16 judgment, award or other payment is  
17 made during such period, then the  
18 last statement of reimbursement  
19 amount that is downloaded during  
20 such period and within 3 business  
21 days before the date of the settlement,  
22 judgment, award, or other payment  
23 shall constitute the final conditional  
24 amount subject to recovery under

1 clause (ii) related to such settlement,  
2 judgment, award, or other payment.

3 “(IV) RESOLUTION OF DISCREP-  
4 ANCIES.—If the individual (or author-  
5 ized representative) believes there is a  
6 discrepancy with the statement of re-  
7 imbursement amount, the Secretary  
8 shall provide a timely process to re-  
9 solve the discrepancy. Under such  
10 process the individual (or representa-  
11 tive) must provide documentation ex-  
12 plaining the discrepancy and a pro-  
13 posal to resolve such discrepancy.  
14 Within 11 business days after the  
15 date of receipt of such documentation,  
16 the Secretary shall determine whether  
17 there is a reasonable basis to include  
18 or remove claims on the statement of  
19 reimbursement. If the Secretary does  
20 not make such determination within  
21 the 11 business-day period, then the  
22 proposal to resolve the discrepancy  
23 shall be accepted. If the Secretary de-  
24 termines within such period that there  
25 is not a reasonable basis to include or

1 remove claims on the statement of re-  
2 imbursement, the proposal shall be re-  
3 jected. If the Secretary determines  
4 within such period that there is a rea-  
5 sonable basis to conclude there is a  
6 discrepancy, the Secretary must re-  
7 spond in a timely manner by agreeing  
8 to the proposal to resolve the discrep-  
9 ancy or by providing documentation  
10 showing with good cause why the Sec-  
11 retary is not agreeing to such pro-  
12 posal and establishing an alternate  
13 discrepancy resolution. In no case  
14 shall the process under this subclause  
15 be treated as an appeals process or as  
16 establishing a right of appeal for a  
17 statement of reimbursement amount  
18 and there shall be no administrative  
19 or judicial review of the Secretary's  
20 determinations under this subclause.

21 “(V) PROTECTED PERIOD.—In  
22 subclause (III), the term ‘protected  
23 period’ means, with respect to a set-  
24 tlement, judgment, award or other  
25 payment relating to an injury or inci-

1                   dent, the portion (if any) of the period  
2                   beginning on the date of notice under  
3                   subclause (I) with respect to such set-  
4                   tlement, judgment, award, or other  
5                   payment that is after the end of a  
6                   Secretarial response period beginning  
7                   on the date of such notice to the Sec-  
8                   retary. Such Secretarial response pe-  
9                   riod shall be a period of 65 days, ex-  
10                  cept that such period may be extended  
11                  by the Secretary for a period of an  
12                  additional 30 days if the Secretary de-  
13                  termines that additional time is re-  
14                  quired to address claims for which  
15                  payment has been made. Such Secre-  
16                  tarial response period shall be ex-  
17                  tended and shall not include any days  
18                  for any part of which the Secretary  
19                  determines (in accordance with regu-  
20                  lations) that there was a failure in the  
21                  claims and payment posting system  
22                  and the failure was justified due to  
23                  exceptional circumstances (as defined  
24                  in such regulations). Such regulations  
25                  shall define exceptional circumstances

1 in a manner so that not more than 1  
2 percent of the repayment obligations  
3 under this subclause would qualify as  
4 exceptional circumstances.

5 “(VI) EFFECTIVE DATE.—The  
6 Secretary shall promulgate final regu-  
7 lations to carry out this clause not  
8 later than 9 months after the date of  
9 the enactment of this clause.

10 “(VII) WEBSITE INCLUDING SUC-  
11 CESSOR TECHNOLOGY.—In this  
12 clause, the term ‘website’ includes any  
13 successor technology.

14 “(viii) RIGHT OF APPEAL FOR SEC-  
15 ONDARY PAYER DETERMINATIONS RELAT-  
16 ING TO LIABILITY INSURANCE (INCLUDING  
17 SELF-INSURANCE), NO FAULT INSURANCE,  
18 AND WORKERS’ COMPENSATION LAWS AND  
19 PLANS.—The Secretary shall promulgate  
20 regulations establishing a right of appeal  
21 and appeals process, with respect to any  
22 determination under this subsection for a  
23 payment made under this title for an item  
24 or service for which the Secretary is seek-  
25 ing to recover conditional payments from

1 an applicable plan (as defined in para-  
2 graph (8)(F)) that is a primary plan under  
3 subsection (A)(ii), under which the applica-  
4 ble plan involved, or an attorney, agent, or  
5 third party administrator on behalf of such  
6 plan, may appeal such determination. The  
7 individual furnished such an item or serv-  
8 ice shall be notified of the plan’s intent to  
9 appeal such determination”.

10 **SEC. 202. FISCAL EFFICIENCY AND REVENUE NEUTRALITY.**

11 (a) IN GENERAL.—Section 1862(b) of the Social Se-  
12 curity Act (42 U.S.C. 1395y(b)) is amended—

13 (1) in paragraph (2)(B)(ii), by striking “A pri-  
14 mary plan” and inserting “Subject to paragraph (9),  
15 a primary plan”; and

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

18 “(9) EXCEPTION.—

19 “(A) IN GENERAL.—Clause (ii) of para-  
20 graph (2)(B) and any reporting required by  
21 paragraph (8) shall not apply with respect to  
22 any settlement, judgment, award, or other pay-  
23 ment by an applicable plan arising from liability  
24 insurance (including self-insurance) and from  
25 alleged physical trauma-based incidents (exclud-

1           ing alleged ingestion, implantation, or exposure  
2           cases) constituting a total payment obligation  
3           to a claimant of not more than the single  
4           threshold amount calculated by the Secretary  
5           under subparagraph (B) for the year involved.

6           “(B) ANNUAL COMPUTATION OF THRESH-  
7           OLD.—

8           “(i) IN GENERAL.—Not later than  
9           November 15 before each year, the Sec-  
10          retary shall calculate and publish a single  
11          threshold amount for settlements, judg-  
12          ments, awards, or other payments for obli-  
13          gations arising from liability insurance (in-  
14          cluding self-insurance) and for alleged  
15          physical trauma-based incidents (excluding  
16          alleged ingestion, implantation, or exposure  
17          cases) subject to this section for that year.  
18          The annual single threshold amount for a  
19          year shall be set such that the estimated  
20          average amount to be credited to the Medi-  
21          care trust funds of collections of condi-  
22          tional payments from such settlements,  
23          judgments, awards, or other payments  
24          arising from liability insurance (including  
25          self-insurance) and for such alleged inci-

1 dents subject to this section shall equal the  
2 estimated cost of collection incurred by the  
3 United States (including payments made  
4 to contractors) for a conditional payment  
5 arising from liability insurance (including  
6 self-insurance) and for such alleged inci-  
7 dents subject to this section for the year.  
8 At the time of calculating, but before pub-  
9 lishing, the single threshold amount for a  
10 year, the Secretary shall inform, and seek  
11 review of, the Comptroller General of the  
12 United States with regard to such amount.

13 “(ii) PUBLICATION.—The Secretary  
14 shall include, as part of such publication  
15 for a year—

16 “(I) the estimated cost of collec-  
17 tion incurred by the United States  
18 (including payments made to contrac-  
19 tors) for a conditional payment aris-  
20 ing from liability insurance (including  
21 self-insurance) and for such alleged  
22 incidents; and

23 “(II) a summary of the method-  
24 ology and data used by the Secretary

1 in computing such threshold amount  
2 and such cost of collection.

3 “(C) EXCLUSION OF ONGOING EX-  
4 PENSES.—For purposes of this paragraph and  
5 with respect to a settlement, judgment, award,  
6 or other payment not otherwise addressed in  
7 clause (ii) of paragraph (2)(B) that includes on-  
8 going responsibility for medical payments (ex-  
9 cluding settlements, judgments, awards, or  
10 other payments made by a workers’ compensa-  
11 tion law or plan or no fault insurance), the  
12 amount utilized for calculation of the threshold  
13 described in subparagraph (A) shall include  
14 only the cumulative value of the medical pay-  
15 ments made under this title.

16 “(D) REPORT TO CONGRESS.—Not later  
17 than November 15 before each year, the Sec-  
18 retary shall submit to the Congress a report on  
19 the single threshold amount for settlements,  
20 judgments, awards, or other payments for con-  
21 ditional payment obligations arising from liabil-  
22 ity insurance (including self-insurance) and al-  
23 leged incidents described in subparagraph (A)  
24 for that year and on the establishment and ap-  
25 plication of similar thresholds for such pay-

1           ments for conditional payment obligations arising from worker compensation cases and from  
2           no fault insurance cases subject to this section  
3           for the year. For each such report, the Secretary shall—

4                           “(i) calculate the threshold amount by  
5                           using the methodology applicable to certain  
6                           liability claims described in subparagraph  
7                           (B); and

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

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

14           **SEC. 203. REPORTING REQUIREMENT.**

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

17                          (1) in the first sentence of subparagraph (E)(i),  
18                          by striking “shall be subject” and all that follows  
19                          through the end of the sentence and inserting the  
20                          following: “may be subject to a civil money penalty

1 of up to \$1,000 for each day of noncompliance with  
2 respect to each claimant.”; and

3 (2) by adding at the end the following new sub-  
4 paragraph:

5 “(I) REGULATIONS.—Not later than 60  
6 days after the date of the enactment of this  
7 subparagraph, the Secretary shall publish a no-  
8 tice in the Federal Register soliciting proposals,  
9 which will be accepted during a 60-day period,  
10 for the specification of practices for which sanc-  
11 tions will and will not be imposed under sub-  
12 paragraph (E), including not imposing sanc-  
13 tions for good faith efforts to identify a bene-  
14 ficiary pursuant to this paragraph under an ap-  
15 plicable entity responsible for reporting infor-  
16 mation. After considering the proposals so sub-  
17 mitted, the Secretary, in consultation with the  
18 Attorney General, shall publish in the Federal  
19 Register, including a 60-day period for com-  
20 ment, proposed specified practices for which  
21 such sanctions will and will not be imposed.  
22 After considering any public comments received  
23 during such period, the Secretary shall issue  
24 final rules specifying such practices.”.

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

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

6 “Not later than 18 months after the date of en-  
7 actment of this sentence, the Secretary shall  
8 modify the reporting requirements under this  
9 paragraph so that an applicable plan in com-  
10 plying with such requirements is permitted but  
11 not required to access or report to the Sec-  
12 retary beneficiary social security account num-  
13 bers or health identification claim numbers, ex-  
14 cept that the deadline for such modification  
15 shall be extended by one or more periods (speci-  
16 fied by the Secretary) of up to 1 year each if  
17 the Secretary notifies the committees of juris-  
18 diction of the House of Representatives and of  
19 the Senate that the prior deadline for such  
20 modification, without such extension, threatens  
21 patient privacy or the integrity of the secondary  
22 payer program under this subsection. Any such  
23 deadline extension notice shall include informa-  
24 tion on the progress being made in imple-  
25 menting such modification and the anticipated  
26 implementation date for such modification.”.

1 **SEC. 205. STATUTE OF LIMITATIONS.**

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

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

Passed the House of Representatives December 19,  
2012.

Attest:

KAREN L. HAAS,  
*Clerk.*