

112TH CONGRESS
2^D SESSION

H. R. 1845

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:

Clerk.

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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.