

**Suspend the Rules And Pass the Bill, H. R. 1845, with Amendments**

**(The amendments strike all after the enacting clause and insert a new text and a new title)**

112<sup>TH</sup> CONGRESS  
1<sup>ST</sup> SESSION

# H. R. 1845

To provide for a study on issues relating to access to intravenous immune globulin (IVIG) for Medicare beneficiaries in all care settings and a demonstration project to examine the benefits of providing coverage and payment for items and services necessary to administer IVIG in the home.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 11, 2011

Mr. BRADY of Texas (for himself, Ms. MATSUI, Mr. BURGESS, Mr. SARBANES, Mr. PAUL, Mr. VAN HOLLEN, Mr. TIBERI, Mr. RUPPERSBERGER, Mrs. BLACKBURN, Mr. SCHIFF, Ms. JENKINS, Mr. KIND, Ms. FUDGE, Ms. RICHARDSON, and Mr. RUSH) introduced the following bill; which was referred to the Committee on Ways and Means, and in addition to the Committee on Energy and Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

To provide for a study on issues relating to access to intravenous immune globulin (IVIG) for Medicare beneficiaries in all care settings and a demonstration project to examine the benefits of providing coverage and payment for items and services necessary to administer IVIG in the home.

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

3 **SECTION 1. SHORT TITLE.**

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

7 **TITLE I—MEDICARE IVIG**  
8 **ACCESS**

9 **SEC. 101. MEDICARE PATIENT IVIG ACCESS DEMONSTRA-**  
10 **TION PROJECT.**

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

18 (b) DURATION AND SCOPE.—

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

23 (2) SCOPE.—The Secretary shall enroll not  
24 more than 4,000 Medicare beneficiaries who have  
25 been diagnosed with primary immunodeficiency dis-

1 ease for participation in the demonstration project.

2 A Medicare beneficiary may participate in the dem-  
3 onstration project on a voluntary basis and may ter-  
4 minate participation at any time.

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

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

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

22 (f) STUDY AND REPORT TO CONGRESS.—

23 (1) INTERIM EVALUATION AND REPORT.—Not  
24 later than three years after the date of enactment of  
25 this Act, the Secretary shall submit to Congress a

1 report that contains an interim evaluation of the im-  
2 pact of the demonstration project on access for  
3 Medicare beneficiaries to items and services needed  
4 for the in-home administration of intravenous im-  
5 mune globin.

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

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

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

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

1           Planning and Evaluation of the Department of  
2           Health and Human Services.

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

8           (h) DEFINITIONS.—In this section:

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

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

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

1 **TITLE II—STRENGTHENING**  
2 **MEDICARE SECONDARY**  
3 **PAYER RULES**

4 **SEC. 201. DETERMINATION OF REIMBURSEMENT AMOUNT**  
5 **THROUGH CMS WEBSITE TO IMPROVE PRO-**  
6 **GRAM EFFICIENCY.**

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

10 “(vii) USE OF WEBSITE TO DETER-  
11 MINE FINAL CONDITIONAL REIMBURSE-  
12 MENT AMOUNT.—

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

1 payment is reasonably expected and  
2 the expected date of such payment.

3 “(II) SECRETARIAL PROVIDING  
4 ACCESS TO CLAIMS INFORMATION  
5 THROUGH A WEBSITE.—The Sec-  
6 retary shall maintain and make avail-  
7 able to individuals to whom items and  
8 services are furnished under this title  
9 (and to authorized family or other  
10 representatives recognized under regu-  
11 lations and to an applicable plan  
12 which has obtained the consent of the  
13 individual) access to information on  
14 the claims for such items and services  
15 (including payment amounts for such  
16 claims), including those claims that  
17 relate to a potential settlement, judg-  
18 ment, award, or other payment . Such  
19 access shall be provided to an indi-  
20 vidual, representative, or plan through  
21 a website that requires a password to  
22 gain access to the information. The  
23 Secretary shall update the information  
24 on claims and payments on such  
25 website in as timely a manner as pos-

1           sible but not later than 15 days after  
2           the date that payment is made. Infor-  
3           mation related to claims and pay-  
4           ments subject to the notice under sub-  
5           clause (I) shall be maintained and  
6           made available consistent with the fol-  
7           lowing:

8                   “(aa) The information shall  
9                   be as complete as possible and  
10                  shall include provider or supplier  
11                  name, diagnosis codes (if any),  
12                  dates of service, and conditional  
13                  payment amounts.

14                  “(bb) The information accu-  
15                  rately identifies those claims and  
16                  payments that are related to a  
17                  potential settlement, judgment,  
18                  award, or other payment to  
19                  which the provisions of this sub-  
20                  section apply.

21                  “(cc) The website provides a  
22                  method for the receipt of secure  
23                  electronic communications with  
24                  the individual, representative, or  
25                  plan involved.

1           “(dd) The website provides  
2           that information is transmitted  
3           from the website in a form that  
4           includes an official time and date  
5           that the information is trans-  
6           mitted.

7           “(ee) The website shall per-  
8           mit the individual, representative,  
9           or plan to download a statement  
10          of reimbursement amounts (in  
11          this clause referred to as a ‘state-  
12          ment of reimbursement amount’)  
13          on payments for claims under  
14          this title relating to a potential  
15          settlement, judgment, award, or  
16          other payment.

17          “(III) USE OF TIMELY WEB  
18          DOWNLOAD AS BASIS FOR FINAL CON-  
19          DITIONAL AMOUNT.—If an individual  
20          (or other claimant or applicable plan  
21          with the consent of the individual) ob-  
22          tains a statement of reimbursement  
23          amount from the website during the  
24          protected period as defined in sub-  
25          clause (V) and the related settlement,

1 judgment, award or other payment is  
2 made during such period, then the  
3 last statement of reimbursement  
4 amount that is downloaded during  
5 such period and within 3 business  
6 days before the date of the settlement,  
7 judgment, award, or other payment  
8 shall constitute the final conditional  
9 amount subject to recovery under  
10 clause (ii) related to such settlement,  
11 judgment, award, or other payment.

12 “(IV) RESOLUTION OF DISCREP-  
13 ANCIES.—If the individual (or author-  
14 ized representative) believes there is a  
15 discrepancy with the statement of re-  
16 imbursement amount, the Secretary  
17 shall provide a timely process to re-  
18 solve the discrepancy. Under such  
19 process the individual (or representa-  
20 tive) must provide documentation ex-  
21 plaining the discrepancy and a pro-  
22 posal to resolve such discrepancy.  
23 Within 11 business days after the  
24 date of receipt of such documentation,  
25 the Secretary shall determine whether

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

1 statement of reimbursement amount  
2 and there shall be no administrative  
3 or judicial review of the Secretary's  
4 determinations under this subclause.

5 “(V) PROTECTED PERIOD.—In  
6 subclause (III), the term ‘protected  
7 period’ means, with respect to a set-  
8 tlement, judgment, award or other  
9 payment relating to an injury or inci-  
10 dent, the portion (if any) of the period  
11 beginning on the date of notice under  
12 subclause (I) with respect to such set-  
13 tlement, judgment, award, or other  
14 payment that is after the end of a  
15 Secretarial response period beginning  
16 on the date of such notice to the Sec-  
17 retary. Such Secretarial response pe-  
18 riod shall be a period of 65 days, ex-  
19 cept that such period may be extended  
20 by the Secretary for a period of an  
21 additional 30 days if the Secretary de-  
22 termines that additional time is re-  
23 quired to address claims for which  
24 payment has been made. Such Secre-  
25 tarial response period shall be ex-

1 tended and shall not include any days  
2 for any part of which the Secretary  
3 determines (in accordance with regu-  
4 lations) that there was a failure in the  
5 claims and payment posting system  
6 and the failure was justified due to  
7 exceptional circumstances (as defined  
8 in such regulations). Such regulations  
9 shall define exceptional circumstances  
10 in a manner so that not more than 1  
11 percent of the repayment obligations  
12 under this subclause would qualify as  
13 exceptional circumstances.

14 “(VI) EFFECTIVE DATE.—The  
15 Secretary shall promulgate final regu-  
16 lations to carry out this clause not  
17 later than 9 months after the date of  
18 the enactment of this clause.

19 “(VII) WEBSITE INCLUDING SUC-  
20 CESSOR TECHNOLOGY.—In this  
21 clause, the term ‘website’ includes any  
22 successor technology.

23 “(viii) RIGHT OF APPEAL FOR SEC-  
24 ONDARY PAYER DETERMINATIONS RELAT-  
25 ING TO LIABILITY INSURANCE (INCLUDING

1 SELF-INSURANCE), NO FAULT INSURANCE,  
2 AND WORKERS' COMPENSATION LAWS AND  
3 PLANS.—The Secretary shall promulgate  
4 regulations establishing a right of appeal  
5 and appeals process, with respect to any  
6 determination under this subsection for a  
7 payment made under this title for an item  
8 or service for which the Secretary is seek-  
9 ing to recover conditional payments from  
10 an applicable plan (as defined in para-  
11 graph (8)(F)) that is a primary plan under  
12 subsection (A)(ii), under which the applica-  
13 ble plan involved, or an attorney, agent, or  
14 third party administrator on behalf of such  
15 plan, may appeal such determination. The  
16 individual furnished such an item or serv-  
17 ice shall be notified of the plan's intent to  
18 appeal such determination”.

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

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

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

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

3           “(9) EXCEPTION.—

4                   “(A) IN GENERAL.—Clause (ii) of para-  
5 graph (2)(B) and any reporting required by  
6 paragraph (8) shall not apply with respect to  
7 any settlement, judgment, award, or other pay-  
8 ment by an applicable plan arising from liability  
9 insurance (including self-insurance) and from  
10 alleged physical trauma-based incidents (exclud-  
11 ing alleged ingestion, implantation, or exposure  
12 cases) constituting a total payment obligation  
13 to a claimant of not more than the single  
14 threshold amount calculated by the Secretary  
15 under subparagraph (B) for the year involved.

16                   “(B) ANNUAL COMPUTATION OF THRESH-  
17 OLD.—

18                   “(i) IN GENERAL.—Not later than  
19 November 15 before each year, the Sec-  
20 retary shall calculate and publish a single  
21 threshold amount for settlements, judg-  
22 ments, awards, or other payments for obli-  
23 gations arising from liability insurance (in-  
24 cluding self-insurance) and for alleged  
25 physical trauma-based incidents (excluding

1           alleged ingestion, implantation, or exposure  
2           cases) subject to this section for that year.  
3           The annual single threshold amount for a  
4           year shall be set such that the estimated  
5           average amount to be credited to the Medi-  
6           care trust funds of collections of condi-  
7           tional payments from such settlements,  
8           judgments, awards, or other payments  
9           arising from liability insurance (including  
10          self-insurance) and for such alleged inci-  
11          dents subject to this section shall equal the  
12          estimated cost of collection incurred by the  
13          United States (including payments made  
14          to contractors) for a conditional payment  
15          arising from liability insurance (including  
16          self-insurance) and for such alleged inci-  
17          dents subject to this section for the year.  
18          At the time of calculating, but before pub-  
19          lishing, the single threshold amount for a  
20          year, the Secretary shall inform, and seek  
21          review of, the Comptroller General of the  
22          United States with regard to such amount.  
23                 “(ii) PUBLICATION.— The Secretary  
24                 shall include, as part of such publication  
25                 for a year—

1                   “(I) the estimated cost of collec-  
2                   tion incurred by the United States  
3                   (including payments made to contrac-  
4                   tors) for a conditional payment aris-  
5                   ing from liability insurance (including  
6                   self-insurance) and for such alleged  
7                   incidents; and

8                   “(II) a summary of the method-  
9                   ology and data used by the Secretary  
10                  in computing such threshold amount  
11                  and such cost of collection.

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

1           “(D) REPORT TO CONGRESS.—Not later  
2 than November 15 before each year, the Sec-  
3 retary shall submit to the Congress a report on  
4 the single threshold amount for settlements,  
5 judgments, awards, or other payments for con-  
6 ditional payment obligations arising from liabil-  
7 ity insurance (including self-insurance) and al-  
8 leged incidents described in subparagraph (A)  
9 for that year and on the establishment and ap-  
10 plication of similar thresholds for such pay-  
11 ments for conditional payment obligations aris-  
12 ing from worker compensation cases and from  
13 no fault insurance cases subject to this section  
14 for the year. For each such report, the Sec-  
15 retary shall—

16           “(i) calculate the threshold amount by  
17 using the methodology applicable to certain  
18 liability claims described in subparagraph  
19 (B); and

20           “(ii) include a summary of the meth-  
21 odology and data used in calculating each  
22 threshold amount and the amount of esti-  
23 mated savings under this title achieved by  
24 the Secretary implementing each such  
25 threshold.”.

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

3 **SEC. 203. REPORTING REQUIREMENT.**

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

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

12 (2) by adding at the end the following new sub-  
13 paragraph:

14 “(I) REGULATIONS.—Not later than 60  
15 days after the date of the enactment of this  
16 subparagraph, the Secretary shall publish a no-  
17 tice in the Federal Register soliciting proposals,  
18 which will be accepted during a 60-day period,  
19 for the specification of practices for which sanc-  
20 tions will and will not be imposed under sub-  
21 paragraph (E), including not imposing sanc-  
22 tions for good faith efforts to identify a bene-  
23 ficiary pursuant to this paragraph under an ap-  
24 plicable entity responsible for reporting infor-  
25 mation. After considering the proposals so sub-

1           mitted, the Secretary, in consultation with the  
2           Attorney General, shall publish in the Federal  
3           Register, including a 60-day period for com-  
4           ment, proposed specified practices for which  
5           such sanctions will and will not be imposed.  
6           After considering any public comments received  
7           during such period, the Secretary shall issue  
8           final rules specifying such practices.”.

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

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

14           “Not later than 18 months after the date of en-  
15           actment of this sentence, the Secretary shall  
16           modify the reporting requirements under this  
17           paragraph so that an applicable plan in com-  
18           plying with such requirements is permitted but  
19           not required to access or report to the Sec-  
20           retary beneficiary social security account num-  
21           bers or health identification claim numbers, ex-  
22           cept that the deadline for such modification  
23           shall be extended by one or more periods (speci-  
24           fied by the Secretary) of up to 1 year each if  
25           the Secretary notifies the committees of juris-

1           diction of the House of Representatives and of  
2           the Senate that the prior deadline for such  
3           modification, without such extension, threatens  
4           patient privacy or the integrity of the secondary  
5           payer program under this subsection. Any such  
6           deadline extension notice shall include informa-  
7           tion on the progress being made in imple-  
8           menting such modification and the anticipated  
9           implementation date for such modification.”.

10 **SEC. 205. STATUTE OF LIMITATIONS.**

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

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

Amend the title so as to read: “A bill 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.”.