

112TH CONGRESS  
1ST SESSION

# H. R. 2195

To amend title XVIII of the Social Security Act to provide for the coverage of home infusion therapy under the Medicare Program.

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## IN THE HOUSE OF REPRESENTATIVES

JUNE 15, 2011

Mr. ENGEL (for himself, Mr. MURPHY of Pennsylvania, and Ms. BALDWIN) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, 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 amend title XVIII of the Social Security Act to provide for the coverage of home infusion therapy under the Medicare Program.

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 Home Infu-  
5 sion Therapy Coverage Act of 2011”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1           (1) The Medicare program is presently the only  
2 major health care payer in the country that does not  
3 provide comprehensive coverage of home infusion  
4 therapy.

5           (2) As a result of the Medicare program not  
6 providing for comprehensive coverage of home infu-  
7 sion therapy, many Medicare beneficiaries are unable  
8 to obtain infusion therapy in the most cost-effective  
9 and convenient setting of their homes.

10          (3) The Medicare program is paying for institu-  
11 tional care for the provision of infusion therapy in  
12 many instances when such institutional care could be  
13 avoided if the Medicare program provided coverage  
14 for home infusion therapy.

15          (4) The Government Accountability Office  
16 found in a 2010 report that home infusion therapy  
17 is utilized widely by private payors providing health  
18 insurance coverage for individuals enrolled under  
19 such coverage and that such private payors generally  
20 are satisfied with the quality of care and the savings  
21 they achieve through avoided institutionalizations.

22 **SEC. 3. MEDICARE COVERAGE OF HOME INFUSION THER-**  
23 **APY.**

24          (a) IN GENERAL.—Section 1861 of the Social Secu-  
25 rity Act (42 U.S.C. 1395x) is amended—

1 (1) in subsection (s)(2)—

2 (A) by striking “and” at the end of sub-  
3 paragraph (EE);

4 (B) by adding “and” at the end of sub-  
5 paragraph (FF); and

6 (C) by adding at the end the following new  
7 subparagraph:

8 “(GG) home infusion therapy (as defined in  
9 subsection (iii)(1));”; and

10 (2) by adding at the end the following new sub-  
11 section:

12 “Home Infusion Therapy

13 “(iii)(1) The term ‘home infusion therapy’ means the  
14 following items and services furnished to an individual,  
15 who is under the care of a physician, which are provided  
16 by a qualified home infusion therapy provider under a plan  
17 (for furnishing such items and services to such individual)  
18 established and periodically reviewed by a physician, which  
19 items and services are provided in an integrated manner  
20 in the individual’s home in conformance with uniform  
21 standards of care established by the Secretary (after tak-  
22 ing into account the standards commonly used for home  
23 infusion therapy by Medicare Advantage plans and in the  
24 private sector and after consultation with all interested

1 stakeholders) and in coordination with the provision of  
2 covered infusion drugs under part D:

3           “(A) Professional services other than nursing  
4 services provided in accordance with the plan (in-  
5 cluding administrative, compounding, dispensing,  
6 distribution, clinical monitoring and care coordina-  
7 tion services) and all necessary supplies and equip-  
8 ment (including medical supplies such as sterile tub-  
9 ing and infusion pumps, and other items and serv-  
10 ices the Secretary determines appropriate) to admin-  
11 ister infusion drug therapies to an individual safely  
12 and effectively in the home.

13           “(B) Nursing services provided in accordance  
14 with the plan, directly by a qualified home infusion  
15 therapy provider or under arrangements with an ac-  
16 credited homecare organization, in connection with  
17 such infusion, except that such term does not in-  
18 clude nursing services to the extent they are covered  
19 as home health services.

20           “(2) For purposes of paragraph (1):

21           “(A) The term ‘home’ means a place of resi-  
22 dence used as an individual’s home and includes  
23 such other alternate settings as the Secretary deter-  
24 mines.

1           “(B) The term ‘qualified home infusion therapy  
2 provider’ means any pharmacy, physician, or other  
3 provider licensed by the State in which the phar-  
4 macy, physician, or provider resides or provides serv-  
5 ices, whose State authorized scope of practice in-  
6 cludes dispensing authority and that—

7           “(i) has expertise in the preparation of  
8 parenteral medications in compliance with en-  
9 forceable standards of the U.S. Pharmacopoeia  
10 and other nationally recognized standards that  
11 regulate preparation of parenteral medications  
12 as determined by the Secretary and meets such  
13 standards;

14           “(ii) provides infusion therapy to patients  
15 with acute or chronic conditions requiring par-  
16 enteral administration of drugs and biologicals  
17 administered through catheters or needles, or  
18 both, in a home; and

19           “(iii) meets such other uniform require-  
20 ments as the Secretary determines are nec-  
21 essary to ensure the safe and effective provision  
22 and administration of home infusion therapy on  
23 a 7 day a week, 24 hour basis (taking into ac-  
24 count the standards of care for home infusion  
25 therapy established by Medicare Advantage

1 plans and in the private sector), and the effi-  
2 cient administration of the home infusion ther-  
3 apy benefit.

4 A qualified home infusion therapy provider may sub-  
5 contract with a pharmacy, physician, provider, or  
6 supplier to meet the requirements of this sub-  
7 section.”.

8 (b) PAYMENT FOR HOME INFUSION THERAPY.—Sec-  
9 tion 1834 of the Social Security Act (42 U.S.C. 1395m)  
10 is amended by adding at the end the following new sub-  
11 section:

12 “(p) PAYMENT FOR HOME INFUSION THERAPY.—  
13 The payment amount under this part for home infusion  
14 therapy is determined as follows:

15 “(1) IN GENERAL.—The Secretary shall deter-  
16 mine a per diem schedule for payment for the pro-  
17 fessional services, supplies, and equipment described  
18 in section 1861(iii)(1)(A) that reflects the reason-  
19 able costs which must be incurred by efficiently and  
20 economically operated qualified home infusion ther-  
21 apy providers to provide such services, supplies, and  
22 equipment in conformity with applicable State and  
23 Federal laws, regulations, and the uniform quality  
24 and safety standards developed under section  
25 1861(iii)(1) and to assure that Medicare bene-

1       ficiaries have reasonable access to such therapy. The  
2       Secretary shall update such schedule from year to  
3       year by the percentage increase in the consumer  
4       price index for all urban consumers (United States  
5       city average) for the 12-month period ending with  
6       June of the preceding year.

7               “(2) NURSING SERVICES.—The Secretary shall  
8       develop a methodology for the separate payment for  
9       nursing services described in section  
10       1861(hhh)(1)(B) provided in accordance with the  
11       plan under such section which reflects the reason-  
12       able costs incurred in the provision of nursing serv-  
13       ices in connection with infusion therapy in con-  
14       formity with State and Federal laws, regulations,  
15       and the uniform quality and safety standards devel-  
16       oped pursuant to this Act and to assure that Medi-  
17       care beneficiaries have reasonable access to nursing  
18       services for infusion therapy. The Secretary shall up-  
19       date such schedule from year to year by the percent-  
20       age increase in the consumer price index for all  
21       urban consumers (United States city average) for  
22       the 12-month period ending with June of the pre-  
23       ceding year.”.

24       (c) CONFORMING AMENDMENTS.—

1           (1)       PAYMENT       REFERENCE.—Section  
2       1833(a)(1) of the Social Security Act (42 U.S.C.  
3       13951(a)(1)) is amended—

4                   (A) by striking “and” before “(Z)”; and

5                   (B) by inserting before the semicolon at  
6       the end the following: “, and (AA) with respect  
7       to home infusion therapy, the amounts paid  
8       shall be determined under section 1834(p)”.

9           (2)       DIRECT PAYMENT.—The first sentence of  
10       section 1842(b)(6) of such Act (42 U.S.C.  
11       1395u(b)(6)) is amended—

12                   (A) by striking “and” before “(H)”; and

13                   (B) by inserting before the period at the  
14       end the following: “, and (I) in the case of  
15       home infusion therapy, payment shall be made  
16       to the qualified home infusion therapy pro-  
17       vider”.

18           (3)       EXCLUSION FROM DURABLE MEDICAL  
19       EQUIPMENT AND HOME HEALTH SERVICES.—Section  
20       1861 of such Act (42 U.S.C. 1395x) is amended—

21                   (A) in subsection (m)(5), by inserting “and  
22       supplies used in the provision of home infusion  
23       therapy” after “excluding other drugs and  
24       biologicals”; and



1 (B) in subsection (n), by adding at the end  
2 the following: “Such term does not include  
3 home infusion therapy, other than equipment  
4 and supplies used in the provision of insulin.”.

5 (4) APPLICATION OF ACCREDITATION PROVI-  
6 SIONS.—The provisions of section 1865(b) of the So-  
7 cial Security Act (42 U.S.C. 1395bb(b)) apply to the  
8 accreditation of qualified home infusion therapy pro-  
9 viders in the manner they apply to other suppliers.

10 **SEC. 4. MEDICARE COVERAGE OF HOME INFUSION DRUGS.**

11 (a) IN GENERAL.—Section 1860D–2(e)(1) of the So-  
12 cial Security Act (42 U.S.C. 1395w–102(e)(1)) is amend-  
13 ed—

14 (1) in paragraph (1)—

15 (A) by striking “or” at the end of subpara-  
16 graph (A);

17 (B) by striking the comma at the end of  
18 subparagraph (B) and inserting “; or”; and

19 (C) by inserting before the flush matter  
20 following subparagraph (B) the following new  
21 subparagraph:

22 “(C) an infusion drug (as defined in para-  
23 graph (5)),”; and

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

1           “(5) INFUSION DRUG DEFINED.—For purposes  
2           of this part, the term ‘infusion drug’ means a paren-  
3           teral drug or biological administered via an intra-  
4           venous, intraspinal, intra-arterial, intrathecal, epidu-  
5           ral, subcutaneous, or intramuscular access device in-  
6           serted into the body, and includes a drug used for  
7           catheter maintenance and de clotting, a drug con-  
8           tained in a device, vitamins, intravenous solutions,  
9           diluent and minerals, and other components used in  
10          the provision of home infusion therapy.”.

11          (b) INFUSION DRUG FORMULARIES.—For the first 2  
12         years after the date of the enactment of this Act, notwith-  
13         standing any other provision of law, prescription drug  
14         plans and MA–PD plans under title XVIII of the Social  
15         Security Act shall maintain open formularies for infusion  
16         drugs (as defined in section 1860D–2(e)(5) of such Act,  
17         as added by subsection (a)). The Secretary of Health and  
18         Human Services shall request the United States Pharma-  
19         ceutical Manufacturers Association to develop, in consultation with representatives of  
20         qualified home infusion therapy providers and other inter-  
21         ested stakeholders, a model formulary approach for home  
22         infusion drugs for use by such plans after such 2-year pe-  
23         riod.

24          (c) PART D DISPENSING FEES.—Section 1860D–  
25         2(d)(1)(B) of the Social Security Act (42 U.S.C. 1395w–

1 102(d)(1)(B)) is amended by inserting after “any dis-  
2 pensing fees for such drugs” the following: “, other than  
3 for an infusion drug”.

4 **SEC. 5. ENSURING BENEFICIARY ACCESS TO HOME INFU-**  
5 **SION THERAPY.**

6 (a) OBJECTIVES IN IMPLEMENTATION.—The Sec-  
7 retary of Health and Human Services shall implement the  
8 Medicare home infusion therapy benefit under the amend-  
9 ments made by this Act in a manner that ensures that  
10 Medicare beneficiaries have timely and appropriate access  
11 to infusion therapy in their homes and that there is rapid  
12 and seamless coordination between drug coverage under  
13 part D of title XVIII of the Social Security Act and cov-  
14 erage for home infusion therapy services under part B of  
15 such title. Specifically, the Secretary shall ensure that—

16 (1) the benefit is practical and workable with  
17 minimal administrative burden for beneficiaries,  
18 qualified home infusion therapy providers, physi-  
19 cians, prescription drug plans, MA–PD plans, and  
20 Medicare Advantage plans, and the Secretary shall  
21 consider the use of consolidated claims encompassing  
22 covered part D drugs and part B services, supplies,  
23 and equipment under such part B to ensure the effi-  
24 cient operation of this benefit;

1           (2) any prior authorization or utilization review  
2 process is expeditious, allowing Medicare bene-  
3 ficiaries meaningful access to home infusion therapy;

4           (3) medical necessity determinations for home  
5 infusion therapy will be made—

6                 (A) except as provided in subparagraph  
7 (B), by medicare administrative contractors  
8 under such part B and communicated to the  
9 appropriate prescription drug plans; or

10                (B) in the case of an individual enrolled in  
11 a Medicare Advantage plan, by the Medicare  
12 Advantage organization offering the plan;

13 and an individual may be initially qualified for cov-  
14 erage for such benefit for a 90-day period and sub-  
15 sequent 90-day periods thereafter;

16           (4) the benefit is modeled on current private  
17 sector coverage and coding for home infusion ther-  
18 apy; and

19           (5) prescription drug plans and MA–PD plans  
20 structure their formularies, utilization review proto-  
21 cols, and policies in a manner that ensures that  
22 Medicare beneficiaries have timely and appropriate  
23 access to infusion therapy in their homes.

24           (b) HOME INFUSION THERAPY ADVISORY PANEL.—

25 In implementing such home infusion therapy benefit and

1 meeting the objectives specified in subsection (a), the Sec-  
2 retary shall establish an advisory panel to provide advice  
3 and recommendations. Such panel shall—

4           (1) be comprised primarily of qualified home in-  
5 fusion therapy providers and their representative or-  
6 ganizations; and

7           (2) also include representatives of the following:

8                   (A) Patient organizations.

9                   (B) Hospital discharge planners, care coor-  
10 dinators, or social workers.

11                   (C) Prescription drug plan sponsors and  
12 Medicare Advantage organizations.

13           (c) REPORT.—Not later than January 1, 2014, and  
14 every 2 years thereafter, the Comptroller General of the  
15 United States shall submit a report to Congress on Medi-  
16 care beneficiary access to home infusion therapy. Each  
17 such report shall specifically address whether the objec-  
18 tives specified in subsection (a) have been met and shall  
19 make recommendations to Congress and the Secretary on  
20 how to improve the benefit and better ensure that Medi-  
21 care beneficiaries have timely and appropriate access to  
22 infusion therapy in their homes.

1 **SEC. 6. EFFECTIVE DATE.**

2       The amendments made by this Act shall apply to  
3 home infusion therapy furnished on or after January 1,  
4 2012.

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