

111TH CONGRESS  
1ST SESSION

# H. R. 574

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

JANUARY 15, 2009

Mr. ENGEL (for himself, Mr. TIM MURPHY of Pennsylvania, Ms. BALDWIN, and Ms. GRANGER) 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 2009”.

1 **SEC. 2. MEDICARE COVERAGE OF HOME INFUSION THER-**  
2 **APY.**

3 (a) IN GENERAL.—Section 1861 of the Social Secu-  
4 rity Act (42 U.S.C. 1395x), as amended by section 152(b)  
5 of the Medicare Improvements for Patients and Providers  
6 Act of 2008 (Public Law 110–275), is amended—

7 (1) in subsection (s)(2)—

8 (A) by striking “and” at the end of sub-  
9 paragraph (DD);

10 (B) by adding “and” at the end of sub-  
11 paragraph (EE); and

12 (C) by adding at the end the following new  
13 subparagraph:

14 “(FF) home infusion therapy (as defined in  
15 subsection (hhh)(1));”; and

16 (2) by adding at the end the following new sub-  
17 section:

18 “Home Infusion Therapy

19 “(hhh)(1) The term ‘home infusion therapy’ means  
20 the following items and services furnished to an individual,  
21 who is under the care of a physician, which are provided  
22 by a qualified home infusion therapy provider under a plan  
23 (for furnishing such items and services to such individual)  
24 established and periodically reviewed by a physician, which  
25 items and services are provided in an integrated manner  
26 in the individual’s home in conformance with uniform

1 standards of care established by the Secretary (after tak-  
2 ing into account the standards commonly used for home  
3 infusion therapy by Medicare Advantage plans and in the  
4 private sector and after consultation with all interested  
5 stakeholders) and in coordination with the provision of  
6 covered infusion drugs under part D:

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

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

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

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

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

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

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

23                 “(iii) meets such other uniform require-  
24                 ments as the Secretary determines are nec-  
25                 essary to ensure the safe and effective provision

1 and administration of home infusion therapy on  
2 a 7 day a week, 24 hour basis (taking into ac-  
3 count the standards of care for home infusion  
4 therapy established by Medicare Advantage  
5 plans and in the private sector), and the effi-  
6 cient administration of the home infusion ther-  
7 apy benefit.

8 A qualified home infusion therapy provider may sub-  
9 contract with a pharmacy, physician, provider, or  
10 supplier to meet the requirements of this sub-  
11 section.”.

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

16 “(n) PAYMENT FOR HOME INFUSION THERAPY.—  
17 The payment amount under this part for home infusion  
18 therapy is determined as follows:

19 “(1) IN GENERAL.—The Secretary shall deter-  
20 mine a per diem schedule for payment for the pro-  
21 fessional services, supplies, and equipment described  
22 in section 1861(hhh)(1)(A) that reflects the reason-  
23 able costs which must be incurred by efficiently and  
24 economically operated qualified home infusion ther-  
25 apy providers to provide such services, supplies, and

1 equipment in conformity with applicable State and  
2 Federal laws, regulations, and the uniform quality  
3 and safety standards developed under section  
4 1861(hhh)(1) and to assure that Medicare bene-  
5 ficiaries have reasonable access to such therapy. The  
6 Secretary shall update such schedule from year to  
7 year by the percentage increase in the consumer  
8 price index for all urban consumers (United States  
9 city average) for the 12-month period ending with  
10 June of the preceding year.

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

1 the 12-month period ending with June of the pre-  
2 ceding year.”.

3 (c) CONFORMING AMENDMENTS.—

4 (1) PAYMENT REFERENCE.—Section  
5 1833(a)(1) of the Social Security Act (42 U.S.C.  
6 13951(a)(1)), as amended by section 101(a)(2) of  
7 the Medicare Improvements for Patients and Pro-  
8 viders Act of 2008 (Public Law 110–275), is amend-  
9 ed—

10 (A) by striking “and” before “(W)”; and

11 (B) by inserting before the semicolon at  
12 the end the following: “, and (X) with respect  
13 to home infusion therapy, the amounts paid  
14 shall be determined under section 1834(n)”.

15 (2) DIRECT PAYMENT.—The first sentence of  
16 section 1842(b)(6) of such Act (42 U.S.C.  
17 1395u(b)(6)) is amended—

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

19 (B) by inserting before the period at the  
20 end the following: “, and (I) in the case of  
21 home infusion therapy, payment shall be made  
22 to the qualified home infusion therapy pro-  
23 vider”.

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

4           (A) in subsection (m)(5), by inserting “and  
5 supplies used in the provision of home infusion  
6 therapy” after “excluding other drugs and  
7 biologicals”; and

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

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

17 **SEC. 3. MEDICARE COVERAGE OF HOME INFUSION DRUGS.**

18          (a) IN GENERAL.—Section 1860D–2(e)(1) of the So-  
19 cial Security Act (42 U.S.C. 1395w–102(e)(1)), as amend-  
20 ed by section 182 of the Medicare Improvements for Pa-  
21 tients and Providers Act of 2008 (Public Law 110–275),  
22 is amended—

23           (1) in paragraph (1)—

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



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

3 (C) by inserting before the flush matter  
4 following subparagraph (B) the following new  
5 subparagraph:

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

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

10 “(5) INFUSION DRUG DEFINED.—For purposes  
11 of this part, the term ‘infusion drug’ means a paren-  
12 teral drug or biological administered via an intra-  
13 venous, intraspinal, intra-arterial, intrathecal, epidu-  
14 ral, subcutaneous, or intramuscular access device in-  
15 serted into the body, and includes a drug used for  
16 catheter maintenance and dec clotting, a drug con-  
17 tained in a device, vitamins, intravenous solutions,  
18 diluents and minerals, and other components used in  
19 the provision of home infusion therapy.”.

20 (b) INFUSION DRUG FORMULARIES.—For the first 2  
21 years after the effective date of this Act, notwithstanding  
22 any other provision of law, prescription drug plans and  
23 MA–PD plans under title XVIII of the Social Security Act  
24 shall maintain open formularies for infusion drugs (as de-  
25 fined in section 1860D–2(e)(5) of such Act, as added by

1 subsection (a)). The Secretary of Health and Human  
 2 Services shall request the United States Pharmacopeia to  
 3 develop, in consultation with representatives of qualified  
 4 home infusion therapy providers and other interested  
 5 stakeholders, a model formulary approach for home infu-  
 6 sion drugs for use by such plans after such 2-year period.

7 (c) PART D DISPENSING FEES.—Section 1860D–  
 8 2(d)(1)(B) of the Social Security Act (42 U.S.C. 1395w–  
 9 102(d)(1)(B)) is amended by inserting after “any dis-  
 10 pensing fees for such drugs” the following: “, other than  
 11 for an infusion drug”.

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

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

24 (1) the benefit is practical and workable with  
 25 minimal administrative burden for beneficiaries,

1 qualified home infusion therapy providers, physi-  
2 cians, prescription drug plans, MA–PD plans, and  
3 Medicare Advantage plans, and the Secretary shall  
4 consider the use of consolidated claims encompassing  
5 covered part D drugs and part B services, supplies,  
6 and equipment under such part B to ensure the effi-  
7 cient operation of this benefit;

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

11 (3) medical necessity determinations for home  
12 infusion therapy will be made—

13 (A) except as provided in subparagraph

14 (B), by medicare administrative contractors  
15 under such part B and communicated to the  
16 appropriate prescription drug plans; or

17 (B) in the case of an individual enrolled in  
18 a Medicare Advantage plan, by the Medicare  
19 Advantage organization offering the plan;

20 and an individual may be initially qualified for cov-  
21 erage for such benefit for a 90-day period and sub-  
22 sequent 90-day periods thereafter;

23 (4) the benefit is modeled on current private  
24 sector coverage and coding for home infusion ther-  
25 apy; and

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

6       (b) HOME INFUSION THERAPY ADVISORY PANEL.—  
7   In implementing such home infusion therapy benefit and  
8   meeting the objectives specified in subsection (a), the Sec-  
9   retary shall establish an advisory panel to provide advice  
10   and recommendations. Such panel shall—

11           (1) be comprised primarily of qualified home in-  
12       fusion therapy providers and their representative or-  
13       ganizations;

14           (2) also include representatives of the following:

15               (1) Patient organizations.

16               (2) Hospital discharge planners, care coordina-  
17       tors, or social workers.

18           (3) Prescription drug plan sponsors and Medi-  
19       care Advantage organizations.

20       (c) REPORT.—Not later than January 1, 2012, and  
21   every 2 years thereafter, the Comptroller General of the  
22   United States shall submit a report to Congress on Medi-  
23   care beneficiary access to home infusion therapy. Each  
24   such report shall specifically address whether the objec-  
25   tives specified in subsection (a) have been met and shall

1 make recommendations to Congress and the Secretary on  
2 how to improve the benefit and better ensure that Medi-  
3 care beneficiaries have timely and appropriate access to  
4 infusion therapy in their homes.

5 **SEC. 5. EFFECTIVE DATE.**

6 The amendments made by this Act shall apply to  
7 home infusion therapy furnished on or after January 1,  
8 2010.

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