

110TH CONGRESS  
1ST SESSION

# H. R. 2567

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 5, 2007

Mr. ENGEL (for himself, Ms. GRANGER, Ms. BALDWIN, Mr. PICKERING, Mr. KUHLMAN, Mr. KUHL of New York, and Mr. TIERNEY) 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 2007”.

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) is amended—

5 (1) in subsection (s)(2)—

6 (A) by striking “and” at the end of sub-  
7 paragraph (Z);

8 (B) by adding “and” at the end of sub-  
9 paragraph (AA); and

10 (C) by adding at the end the following new  
11 subparagraph:

12 “(BB) home infusion therapy (as defined in  
13 subsection (ccc)(1));”; and

14 (2) by adding at the end the following new sub-  
15 section:

16 “Home Infusion Therapy

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

1 infusion therapy by Medicare Advantage plans and in the  
2 private sector and after consultation with all interested  
3 stakeholders) and in coordination with the provision of  
4 covered infusion drugs under part D:

5           “(A) Professional services other than nursing  
6           services (including administrative, compounding, dis-  
7           pensing, distribution, clinical monitoring and care  
8           coordination services) and all necessary supplies and  
9           equipment (including medical supplies such as sterile  
10          tubing and infusion pumps, and other items and  
11          services the Secretary determines appropriate) to ad-  
12          minister infusion drug therapies to an individual  
13          safely and effectively in the home.

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

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

22                 “(A) The term ‘home’ means a place of resi-  
23                 dence used as an individual’s home and includes  
24                 such other alternate settings as the Secretary deter-  
25                 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 seven day a week, twenty-four hour basis  
24 (taking into account the standards of care for  
25 home infusion therapy established by Medicare

1 Advantage plans and in the private sector), and  
2 the efficient administration of the home infu-  
3 sion therapy benefit.

4 A qualified home infusion provider may subcontract  
5 with a pharmacy, physician, provider, or supplier to  
6 meet the requirements of this subsection.”.

7 (b) PAYMENT FOR HOME INFUSION THERAPY.—Sec-  
8 tion 1834 of such Act (42 U.S.C. 1395m) is amended by  
9 adding at the end the following new subsection:

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

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

1 year by the percentage increase in the consumer  
2 price index for all urban consumers (United States  
3 city average) for the 12-month period ending with  
4 June of the preceding year.

5 “(2) NURSING SERVICES.—The Secretary shall  
6 develop a methodology for the separate payment for  
7 nursing services described in section 1861(ccc)(1)(B)  
8 provided in accordance with the plan under such sec-  
9 tion which reflects the reasonable costs incurred in  
10 the provision of nursing services in connection with  
11 infusion therapy in conformity with State and Fed-  
12 eral laws, regulations, and the uniform quality and  
13 safety standards developed pursuant to this Act and  
14 to assure that Medicare beneficiaries have reason-  
15 able access to nursing services for infusion therapy.  
16 The Secretary shall update such schedule from year  
17 to year by the percentage increase in the consumer  
18 price index for all urban consumers (United States  
19 city average) for the 12-month period ending with  
20 June of the preceding year.”.

21 (c) CONFORMING AMENDMENTS.—

22 (1) PAYMENT REFERENCE.—Section  
23 1833(a)(1) of the Social Security Act (42 U.S.C.  
24 13951(a)(1)) is amended—

25 (A) by striking “and” before “(V)”; and

1 (B) by inserting before the semicolon at  
2 the end the following: “, and (W) with respect  
3 to home infusion therapy, the amounts paid  
4 shall be determined under section 1834(n)”.

5 (2) DIRECT PAYMENT.—The first sentence of  
6 section 1842(b)(6) of such Act (42 U.S.C.  
7 1395u(b)(6)) is amended—

8 (A) by striking “and” before “(H)”;

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

14 (3) EXCLUSION FROM DURABLE MEDICAL  
15 EQUIPMENT AND HOME HEALTH SERVICES.—Section  
16 1861 of such Act (42 U.S.C. 1395x) is amended—

17 (A) in subsection (m), by inserting “and  
18 supplies used in the provision of home infusion  
19 therapy” after “excluding other drugs and  
20 biologicals”; and

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

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

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

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

10           (1) in paragraph (1)—

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

13           (B) by striking the comma at the end of  
14           subparagraph (B) and inserting “, or”; and

15           (C) by inserting after subparagraph (B)  
16           the following new subparagraph:

17           “(C) an infusion drug (as defined in para-  
18           graph (4)),”; and

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

21           “(4) INFUSION DRUG DEFINED.—For purposes  
22           of this part, the term ‘infusion drug’ means a paren-  
23           teral drug or biological administered via an intra-  
24           venous, intraspinal, intra-arterial, intrathecal, epidu-  
25           ral, subcutaneous, or intramuscular access device in-

1       serted into the body, and includes a drug used for  
2       catheter maintenance and dec clotting, a drug con-  
3       tained in a device, vitamins, intravenous solutions,  
4       dil uents and minerals, and other components used in  
5       the provision of home infusion therapy.”.

6       (b) INFUSION DRUG FORMULARIES.—For the first 2  
7       years after the effective date of this Act, notwithstanding  
8       any other provision of law, prescription drug plans and  
9       MA–PD plans under title XVIII of the Social Security Act  
10      shall maintain open formularies for infusion drugs (as de-  
11      fined in section 1860D–2(e)(4) of such Act. The Secretary  
12      of Health and Human Services shall request the United  
13      States Pharmacopeia to develop, in consultation with rep-  
14      resentatives of qualified home infusion therapy providers  
15      and other interested stakeholders, a model formulary ap-  
16      proach for home infusion drugs for use by such plans after  
17      such 2-year period.

18      (c) PART D DISPENSING FEES.—Section 1860D–  
19      2(d)(1)(B) of the Social Security Act (42 U.S.C. 1395w–  
20      102(d)(1)(B)) is amended by inserting after “any dis-  
21      pensing fees for such drugs” the following: “, other than  
22      for an infusion drug”.

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

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

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

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

25 (3) medical necessity determinations for home  
26 infusion therapy will be made by Medicare adminis-

1 trative contractors under such part B and commu-  
2 nicated to the appropriate prescription drug plans  
3 and MA–PD plans and an individual may be initially  
4 qualified for coverage for such benefit for a 90-day  
5 period and subsequent 90-day periods thereafter;

6 (4) the benefit is modeled on current private  
7 sector coverage and coding for home infusion ther-  
8 apy; and

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

14 (b) HOME INFUSION THERAPY ADVISORY PANEL.—  
15 In implementing such home infusion therapy benefit and  
16 meeting the objectives specified in subsection (a), the Sec-  
17 retary shall establish an advisory panel comprised of quali-  
18 fied home infusion therapy providers and their representa-  
19 tive organizations as well as representatives of the fol-  
20 lowing to provide advice and recommendations:

21 (1) Patient organizations.

22 (2) Hospital discharge planners, care coordina-  
23 tors or social workers.

24 (3) Prescription drug plan sponsors and Medi-  
25 care Advantage organizations.

1 (c) REPORT.—Not later than January 1, 2010, and  
2 every two years thereafter, the Comptroller General of the  
3 United States shall submit a report to Congress on Medi-  
4 care beneficiary access to home infusion therapy. Each  
5 such report shall specifically address whether the objec-  
6 tives specified in subsection (a) have been met and shall  
7 make recommendations to Congress and the Secretary on  
8 how to improve the benefit and better ensure that Medi-  
9 care beneficiaries have timely and appropriate access to  
10 infusion therapy in their homes.

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

12 The amendments made by this Act shall apply to  
13 home infusion therapy furnished on or after January 1,  
14 2008.

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