

110TH CONGRESS  
2D SESSION

# S. 3505

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 SENATE OF THE UNITED STATES

SEPTEMBER 17, 2008

Mrs. LINCOLN (for herself, Ms. SNOWE, and Mr. ISAKSON) introduced the following bill; which was read twice and referred to the Committee on Finance

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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 2008”.

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

8 (a) IN GENERAL.—Section 1861 of the Social Secu-  
9 rity Act (42 U.S.C. 1395x), as amended by section 152(b)

1 of the Medicare Improvements for Patients and Providers  
2 Act of 2008 (Public Law 110–275), is amended—

3 (1) in subsection (s)(2)—

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

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

8 (C) by adding at the end the following new  
9 subparagraph:

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

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

14 “Home Infusion Therapy

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

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

4           “(A) Professional services other than nursing  
5           services (including administrative, compounding, dis-  
6           pensing, distribution, clinical monitoring and care  
7           coordination services) and all necessary supplies and  
8           equipment (including medical supplies such as sterile  
9           tubing and infusion pumps, and other items and  
10          services the Secretary determines appropriate) to ad-  
11          minister infusion drug therapies to an individual  
12          safely 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 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 the Social Security Act (42 U.S.C. 1395m)  
9 is amended by adding at the end the following new sub-  
10 section:

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

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

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

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

23 (c) CONFORMING AMENDMENTS.—

24 (1) PAYMENT REFERENCE.—Section  
25 1833(a)(1) of the Social Security Act (42 U.S.C.

1 13951(a)(1)), as amended by section 101(a)(2) of  
2 the Medicare Improvements for Patients and Pro-  
3 viders Act of 2008 (Public Law 110–275), is amend-  
4 ed—

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

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

10 (2) DIRECT PAYMENT.—The first sentence of  
11 section 1842(b)(6) of such Act (42 U.S.C.  
12 1395u(b)(6)) is amended—

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

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

19 (3) EXCLUSION FROM DURABLE MEDICAL  
20 EQUIPMENT AND HOME HEALTH SERVICES.—Section  
21 1861 of such Act (42 U.S.C. 1395x) is amended—

22 (A) in subsection (m)(5), by inserting “and  
23 supplies used in the provision of home infusion  
24 therapy” after “excluding other drugs and  
25 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. 3. 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)), as amend-  
 13 ed by section 182 of the Medicare Improvements for Pa-  
 14 tients and Providers Act of 2008 (Public Law 110–275),  
 15 is amended—

16 (1) in paragraph (1)—

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

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

21 (C) by inserting before the flush matter  
 22 following subparagraph (B) the following new  
 23 subparagraph:

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

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

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

13          (b) INFUSION DRUG FORMULARIES.—For the first 2  
14 years after the effective date of this Act, notwithstanding  
15 any other provision of law, prescription drug plans and  
16 MA–PD plans under title XVIII of the Social Security Act  
17 shall maintain open formularies for infusion drugs (as de-  
18 fined in section 1860D–2(e)(5) of such Act, as added by  
19 subsection (a)). The Secretary of Health and Human  
20 Services shall request the United States Pharmacopeia to  
21 develop, in consultation with representatives of qualified  
22 home infusion therapy providers and other interested  
23 stakeholders, a model formulary approach for home infu-  
24 sion drugs for use by such plans after such 2-year period.

1 (c) PART D DISPENSING FEES.—Section 1860D–  
2 2(d)(1)(B) of the Social Security Act (42 U.S.C. 1395w–  
3 102(d)(1)(B)) is amended by inserting after “any dis-  
4 pensing fees for such drugs” the following: “, other than  
5 for an infusion drug”.

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

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

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

1 and equipment under such part B to ensure the effi-  
2 cient operation of this benefit;

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

6 (3) medical necessity determinations for home  
7 infusion therapy will be made by Medicare adminis-  
8 trative contractors under such part B and commu-  
9 nicated to the appropriate prescription drug plans  
10 and MA–PD plans and an individual may be initially  
11 qualified for coverage for such benefit for a 90-day  
12 period and subsequent 90-day periods thereafter;

13 (4) the benefit is modeled on current private  
14 sector coverage and coding for home infusion ther-  
15 apy; and

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

21 (b) HOME INFUSION THERAPY ADVISORY PANEL.—

22 In implementing such home infusion therapy benefit and  
23 meeting the objectives specified in subsection (a), the Sec-  
24 retary shall establish an advisory panel comprised of quali-  
25 fied home infusion therapy providers and their representa-

1 tive organizations as well as representatives of the fol-  
2 lowing to provide advice and recommendations:

3 (1) Patient organizations.

4 (2) Hospital discharge planners, care coordina-  
5 tors, or social workers.

6 (3) Prescription drug plan sponsors and Medi-  
7 care Advantage organizations.

8 (c) REPORT.—Not later than January 1, 2011, and  
9 every 2 years thereafter, the Comptroller General of the  
10 United States shall submit a report to Congress on Medi-  
11 care beneficiary access to home infusion therapy. Each  
12 such report shall specifically address whether the objec-  
13 tives specified in subsection (a) have been met and shall  
14 make recommendations to Congress and the Secretary on  
15 how to improve the benefit and better ensure that Medi-  
16 care beneficiaries have timely and appropriate access to  
17 infusion therapy in their homes.

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

19 The amendments made by this Act shall apply to  
20 home infusion therapy furnished on or after January 1,  
21 2009.

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