

114TH CONGRESS  
1ST SESSION

# S. 275

To amend title XVIII of the Social Security Act to provide for the coverage of home as a site of care for infusion therapy under the Medicare program.

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IN THE SENATE OF THE UNITED STATES

JANUARY 28, 2015

Mr. ISAKSON (for himself and Mr. WARNER) 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 as a site of care for 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 Site of Care Act of 2015”.

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) is amended—

10 (1) in subsection (s)(2)—

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

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

5 (C) by inserting at the end the following  
6 new subparagraph:

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

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

11 “Home Infusion Therapy

12 “(iii)(1) The term ‘home infusion therapy’ means the  
13 items and services described in paragraph (2) furnished  
14 to an individual, who is under the care of a physician,  
15 which are provided by a qualified home infusion therapy  
16 supplier under a plan (for furnishing such items and serv-  
17 ices to such individual) established and periodically re-  
18 viewed by a physician, which items and services are pro-  
19 vided in an integrated manner in the individual’s home  
20 in conformance with uniform standards of care established  
21 by the Secretary and in coordination with the provision  
22 of covered infusion drugs under part D. The Secretary  
23 shall establish such standards after taking into account  
24 the standards commonly used for home infusion therapy

1 by Medicare Advantage plans and in the private sector and  
2 after consultation with all interested stakeholders.

3 “(2) The items and services described in this para-  
4 graph are the following:

5 “(A) Professional services, including nursing  
6 services (other than nursing services covered as  
7 home health services), provided in accordance with  
8 the plan (including administrative, compounding,  
9 dispensing, distribution, clinical monitoring, and  
10 care coordination services) and all necessary supplies  
11 and equipment (including medical supplies such as  
12 sterile tubing and infusion pumps).

13 “(B) Other items and services the Secretary de-  
14 termines appropriate to administer infusion drug  
15 therapies to an individual safely and effectively in  
16 the home.

17 “(3) For purposes of this subsection:

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

22 “(B) The term ‘qualified home infusion therapy  
23 supplier’ means any pharmacy, physician, or other  
24 provider licensed by the State in which the phar-  
25 macy, physician, or provider resides or provides serv-

1 ices, whose State authorized scope of practice in-  
2 cludes dispensing authority and that—

3 “(i) has expertise in the preparation of  
4 parenteral medications in compliance with en-  
5 forceable standards of the United States Phar-  
6 macopoeia and other nationally recognized  
7 standards that regulate preparation of paren-  
8 teral medications as determined by the Sec-  
9 retary and meets such standards;

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

15 “(iii) meets such other uniform require-  
16 ments as the Secretary determines are nec-  
17 essary to ensure the safe and effective provision  
18 and administration of home infusion therapy on  
19 a 7-day-a-week, 24-hour basis (taking into ac-  
20 count the standards of care for home infusion  
21 therapy established by Medicare Advantage  
22 plans and in the private sector), and the effi-  
23 cient administration of the home infusion ther-  
24 apy benefit.

1 “(4) A qualified home infusion therapy supplier may  
2 subcontract with a pharmacy, physician, provider, or sup-  
3 plier to meet the requirements of paragraph (3)(B).”.

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

8 “(r) PAYMENT FOR HOME INFUSION THERAPY.—

9 “(1) IN GENERAL.—The Secretary shall deter-  
10 mine a per diem schedule for payment for the pro-  
11 fessional services (including nursing services), sup-  
12 plies, and equipment described in section  
13 1861(iii)(2)(A) for each infusion therapy type that  
14 reflects the reasonable costs which must be incurred  
15 by efficiently and economically operated qualified  
16 home infusion therapy suppliers to provide such  
17 services, supplies, and equipment in conformity with  
18 applicable State and Federal laws, regulations, and  
19 the uniform quality and safety standards developed  
20 under section 1861(iii)(1) and to assure that Medi-  
21 care beneficiaries have reasonable access to such  
22 therapy.

23 “(2) CONSIDERATIONS.—In developing the per  
24 diem schedule under this subsection, the Secretary  
25 shall consider recent credible studies about the costs

1 of providing infusion therapy in the home, consult  
2 with home infusion therapy suppliers, consider pay-  
3 ment amounts established by Medicare Advantage  
4 plans and private payers for home infusion therapy,  
5 and, if necessary, conduct a statistically valid na-  
6 tional market analysis involving the costs of admin-  
7 istering infusion drugs and of providing professional  
8 services necessary for the drugs' administration.

9 “(3) ANNUAL UPDATES.—The Secretary shall  
10 update such schedule from year to year by the per-  
11 centage increase in the Consumer Price Index for all  
12 urban consumers (United States city average) for  
13 the 12-month period ending with June of the pre-  
14 ceding year. The Secretary may modify the per diem  
15 schedule with respect to beneficiaries who qualify for  
16 home infusion therapy services under section  
17 1861(iii)(1) but who receive nursing services as  
18 home health services.”.

19 (c) CONFORMING AMENDMENTS.—

20 (1) PAYMENT REFERENCE.—Section  
21 1833(a)(1) of the Social Security Act (42 U.S.C.  
22 1395l(a)(1)) is amended—

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

24 (B) by inserting before the semicolon at

25 the end the following: “, and (AA) with respect

1 to home infusion therapy, the amounts paid  
2 shall be determined under section 1834(r)”.

3 (2) DIRECT PAYMENT.—The first sentence of  
4 section 1842(b)(6) of the Social Security Act (42  
5 U.S.C. 1395u(b)(6)) is amended—

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

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

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

16 (A) in subsection (m)(5)—

17 (i) by striking “and” before “durable  
18 medical equipment” and inserting a  
19 comma; and

20 (ii) by inserting before the semicolon  
21 at the end the following: “, and supplies  
22 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(a) of the So-  
7 cial Security Act (42 U.S.C. 1395bb(a)) apply to the  
8 accreditation of qualified home infusion therapy sup-  
9 pliers in the same way as they apply to other sup-  
10 pliers.

11 **SEC. 3. HOME INFUSION DRUGS.**

12 Section 1860D–2(e) of the Social Security Act (42  
13 U.S.C. 1395w–102(e)) is amended—

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 after subparagraph (B)  
20 the following new subparagraph:

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

23 (2) by adding at the end the following new  
24 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 or  
6           injection, and may include a drug used for catheter  
7           maintenance and dec clotting, a drug contained in a  
8           device, additives including but not limited to vita-  
9           mins, minerals, solutions, and diluents, and other  
10          components used in the provision of home infusion  
11          therapy.”.

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 to avoid the filing of duplicative or otherwise  
24          improper claims. Specifically, the Secretary shall ensure  
25          that—

1           (1) the benefit is practical and workable with  
2           minimal administrative burden for beneficiaries,  
3           qualified home infusion therapy suppliers, physi-  
4           cians, prescription drug plans, MA–PD plans, and  
5           Medicare Advantage plans, and the Secretary shall  
6           consider the use of consolidated claims encompassing  
7           covered part D drugs and part B services, supplies,  
8           and equipment under such part B to ensure the effi-  
9           cient operation of this benefit;

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

13           (3) medical necessity determinations for home  
14           infusion therapy will be made—

15                   (A) except as provided in subparagraph  
16                   (B), by Medicare administrative contractors  
17                   under such part B and communicated to the  
18                   appropriate prescription drug plans; or

19                   (B) in the case of an individual enrolled in  
20                   a Medicare Advantage plan, by the Medicare  
21                   Advantage organization offering the plan; and  
22                   an individual may be initially qualified for cov-  
23                   erage for such benefit for a 90-day period and  
24                   subsequent 90-day periods thereafter;

1 (4) except as otherwise provided in this section,  
2 the benefit is modeled on current private sector cov-  
3 erage and coding for home infusion therapy; and

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

9 (b) REPORT.—Not later than January 1, 2018, the  
10 Comptroller General of the United States shall submit to  
11 Congress a report on Medicare beneficiary access to home  
12 infusion therapy. Such report shall specifically address  
13 whether the objectives specified in subsection (a) have  
14 been met and shall make recommendations to Congress  
15 and the Secretary of Health and Human Services on how  
16 to improve the benefit and better ensure that Medicare  
17 beneficiaries have timely and appropriate access to infu-  
18 sion therapy in their homes.

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

20 The amendments made by this Act shall apply to  
21 home infusion therapy furnished on or after January 1,  
22 2016.

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