

113TH CONGRESS  
2D SESSION

# H. R. 5435

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 HOUSE OF REPRESENTATIVES

SEPTEMBER 10, 2014

Mr. ENGEL (for himself, Mr. TIBERI, Mr. LARSON of Connecticut, Mr. HARPER, Mr. MEEHAN, Ms. PINGREE of Maine, and Mr. PETERSON) 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 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 2014”.

6 **SEC. 2. FINDINGS.**

7 Congress finds the following:

1           (1) The Medicare fee-for-service program covers  
2           infusion therapy in the hospital, skilled nursing facil-  
3           ity, physician office, and hospital outpatient depart-  
4           ment, but does not cover the full range of services  
5           for the provision of infusion therapies in a patient's  
6           home.

7           (2) The Medicare program is presently the only  
8           major health care payer in the United States that  
9           does not provide comprehensive coverage of home in-  
10          fusion therapy.

11          (3) As a result of the Medicare program not  
12          providing for comprehensive coverage of home infu-  
13          sion therapy, many Medicare beneficiaries are unable  
14          to obtain infusion therapy in the most cost-effective  
15          and convenient setting of their home, and physicians  
16          are deprived of the ability to select the best site of  
17          care for their patients.

18          (4) The Medicare program is paying for institu-  
19          tional care for the provision of infusion therapy in  
20          many instances when such institutional care could be  
21          avoided if the Medicare program provided coverage  
22          for home infusion therapy.

23          (5) The Government Accountability Office  
24          found in a 2010 report that home infusion therapy  
25          is utilized widely by private payers providing health

1 insurance coverage for individuals enrolled under  
2 such coverage and that such private payers generally  
3 are satisfied with the quality of care and the savings  
4 they achieve through avoided institutionalizations.

5 (6) A recent study has reported a potential sav-  
6 ings for Medicare if infusion therapies were covered  
7 in the home site of care.

8 **SEC. 3. MEDICARE COVERAGE OF HOME INFUSION THER-**  
9 **APY.**

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

12 (1) in subsection (s)(2)—

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

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

17 (C) by inserting at the end the following  
18 new subparagraph:

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

21 (2) by adding at the end the following new sub-  
22 section:

23 “Home Infusion Therapy

24 “(iii)(1) The term ‘home infusion therapy’ means the  
25 items and services described in paragraph (2) furnished

1 to an individual, who is under the care of a physician,  
2 which are provided by a qualified home infusion therapy  
3 supplier under a plan (for furnishing such items and serv-  
4 ices to such individual) established and periodically re-  
5 viewed by a physician, which items and services are pro-  
6 vided in an integrated manner in the individual's home  
7 in conformance with uniform standards of care established  
8 by the Secretary and in coordination with the provision  
9 of covered infusion drugs under part D. The Secretary  
10 shall establish such standards after taking into account  
11 the standards commonly used for home infusion therapy  
12 by Medicare Advantage plans and in the private sector and  
13 after consultation with all interested stakeholders.

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

16               “(A) Professional services, including nursing  
17 services (other than nursing services covered as  
18 home health services), provided in accordance with  
19 the plan (including administrative, compounding,  
20 dispensing, distribution, clinical monitoring, and  
21 care coordination services) and all necessary supplies  
22 and equipment (including medical supplies such as  
23 sterile tubing and infusion pumps).

24               “(B) Other items and services the Secretary de-  
25 termines appropriate to administer infusion drug

1 therapies to an individual safely and effectively in  
2 the home.

3 “(3) For purposes of this subsection:

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

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

14 “(i) has expertise in the preparation of  
15 parenteral medications in compliance with en-  
16 forceable standards of the United States Phar-  
17 macopoeia and other nationally recognized  
18 standards that regulate preparation of paren-  
19 teral medications as determined by the Sec-  
20 retary and meets such standards;

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

1           “(iii) meets such other uniform require-  
2           ments as the Secretary determines are nec-  
3           essary to ensure the safe and effective provision  
4           and administration of home infusion therapy on  
5           a 7-day-a-week, 24-hour basis (taking into ac-  
6           count the standards of care for home infusion  
7           therapy established by Medicare Advantage  
8           plans and in the private sector), and the effi-  
9           cient administration of the home infusion ther-  
10          apy benefit.

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

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

18          “(p) PAYMENT FOR HOME INFUSION THERAPY.—

19                 “(1) IN GENERAL.—The Secretary shall deter-  
20                 mine a per diem schedule for payment for the pro-  
21                 fessional services (including nursing services), sup-  
22                 plies, and equipment described in section  
23                 1861(iii)(2)(A) for each infusion therapy type that  
24                 reflects the reasonable costs which must be incurred  
25                 by efficiently and economically operated qualified

1 home infusion therapy suppliers to provide such  
2 services, supplies, and equipment in conformity with  
3 applicable State and Federal laws, regulations, and  
4 the uniform quality and safety standards developed  
5 under section 1861(iii)(1) and to assure that Medi-  
6 care beneficiaries have reasonable access to such  
7 therapy.

8 “(2) CONSIDERATIONS.—In developing the per  
9 diem schedule under this subsection, the Secretary  
10 shall consider recent credible studies about the costs  
11 of providing infusion therapy in the home, consult  
12 with home infusion therapy suppliers, consider pay-  
13 ment amounts established by Medicare Advantage  
14 plans and private payers for home infusion therapy,  
15 and, if necessary, conduct a statistically valid na-  
16 tional market analysis involving the costs of admin-  
17 istering infusion drugs and of providing professional  
18 services necessary for the drugs’ administration.

19 “(3) ANNUAL UPDATES.—The Secretary shall  
20 update such schedule from year to year by the per-  
21 centage increase in the Consumer Price Index for all  
22 urban consumers (United States city average) for  
23 the 12-month period ending with June of the pre-  
24 ceding year. The Secretary may modify the per diem  
25 schedule with respect to beneficiaries who qualify for

1 home infusion therapy services under section  
2 1861(iii)(1) but who receive nursing services as  
3 home health services.”.

4 (c) CONFORMING AMENDMENTS.—

5 (1) PAYMENT REFERENCE.—Section  
6 1833(a)(1) of the Social Security Act (42 U.S.C.  
7 13951(a)(1)) is amended—

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

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

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

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

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

22 (3) EXCLUSION FROM DURABLE MEDICAL  
23 EQUIPMENT AND HOME HEALTH SERVICES.—Section  
24 1861 of the Social Security Act (42 U.S.C. 1395x)  
25 is amended—



1 (A) in subsection (m)(5)—

2 (i) by striking “and” before “durable  
3 medical equipment” and inserting a  
4 comma; and

5 (ii) by inserting before the semicolon  
6 at the end the following: “, and supplies  
7 used in the provision of home infusion  
8 therapy after excluding other drugs and  
9 biologicals”; and

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

14 (4) APPLICATION OF ACCREDITATION PROVI-  
15 SIONS.—The provisions of section 1865(a) of the So-  
16 cial Security Act (42 U.S.C. 1395bb(a)) apply to the  
17 accreditation of qualified home infusion therapy sup-  
18 pliers in the same way as they apply to other sup-  
19 pliers.

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

21 Section 1860D–2(e) of the Social Security Act (42  
22 U.S.C. 1395w–102(e)) 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 after subparagraph (B)  
4 the following new subparagraph:

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

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

9 “(5) INFUSION DRUG DEFINED.—For purposes  
10 of this part, the term ‘infusion drug’ means a paren-  
11 teral drug or biological administered via an intra-  
12 venous, intraspinal, intra-arterial, intrathecal, epidu-  
13 ral, subcutaneous, or intramuscular access device or  
14 injection, and may include a drug used for catheter  
15 maintenance and declotting, a drug contained in a  
16 device, additives including but not limited to vita-  
17 mins, minerals, solutions, and diluents, and other  
18 components used in the provision of home infusion  
19 therapy.”.

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

22 (a) OBJECTIVES IN IMPLEMENTATION.—The Sec-  
23 retary of Health and Human Services shall implement the  
24 Medicare home infusion therapy benefit under the amend-  
25 ments made by this Act in a manner that ensures that

1 Medicare beneficiaries have timely and appropriate access  
2 to infusion therapy in their homes and that there is rapid  
3 and seamless coordination between drug coverage under  
4 part D of title XVIII of the Social Security Act and cov-  
5 erage for home infusion therapy services under part B of  
6 such title to avoid the filing of duplicative or otherwise  
7 improper claims. Specifically, the Secretary shall ensure  
8 that—

9           (1) the benefit is practical and workable with  
10 minimal administrative burden for beneficiaries,  
11 qualified home infusion therapy suppliers, physi-  
12 cians, prescription drug plans, MA–PD plans, and  
13 Medicare Advantage plans, and the Secretary shall  
14 consider the use of consolidated claims encompassing  
15 covered part D drugs and part B services, supplies,  
16 and equipment under such part B to ensure the effi-  
17 cient operation of this benefit;

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

21           (3) medical necessity determinations for home  
22 infusion therapy will be made—

23                   (A) except as provided in subparagraph

24                   (B), by Medicare administrative contractors

1 under such part B and communicated to the  
2 appropriate prescription drug plans; or

3 (B) in the case of an individual enrolled in  
4 a Medicare Advantage plan, by the Medicare  
5 Advantage organization offering the plan; and  
6 an individual may be initially qualified for cov-  
7 erage for such benefit for a 90-day period and  
8 subsequent 90-day periods thereafter;

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

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

17 (b) REPORT.—Not later than January 1, 2018, the  
18 Comptroller General of the United States shall submit a  
19 report to Congress on Medicare beneficiary access to home  
20 infusion therapy. Such report shall specifically address  
21 whether the objectives specified in subsection (a) have  
22 been met and shall make recommendations to Congress  
23 and the Secretary of Health and Human Services on how  
24 to improve the benefit and better ensure that Medicare

1 beneficiaries have timely and appropriate access to infu-  
2 sion therapy in their homes.

3 **SEC. 6. EFFECTIVE DATE.**

4       The amendments made by this Act shall apply to  
5 home infusion therapy furnished on or after January 1,  
6 2015.

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