

114TH CONGRESS
1ST SESSION

S. _____

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.

IN THE SENATE OF THE UNITED STATES

Mr. ISAKSON (for himself and Mr. WARNER) introduced the following bill; which was read twice and referred to the Committee on

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—

1 (1) in subsection (s)(2)—

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

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

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

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

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

12 “Home Infusion Therapy

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