

114TH CONGRESS
1ST SESSION

H. R. 605

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, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 28, 2015

Mr. ENGEL (for himself, Mr. TIBERI, Mr. HARPER, Ms. PINGREE, Mr. LARSON of Connecticut, 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

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, and for other purposes.

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”.

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 (EE);

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

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

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

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

16 “Home Infusion Therapy

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

1 of covered infusion drugs under part D. The Secretary
2 shall establish such standards after taking into account
3 the standards commonly used for home infusion therapy
4 by Medicare Advantage plans and in the private sector and
5 after consultation with all interested stakeholders.

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

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

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

20 “(3) For purposes of this subsection:

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 supplier’ 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 United States Phar-
10 macopoeia and other nationally recognized
11 standards that regulate preparation of paren-
12 teral medications as determined by the Sec-
13 retary and meets such 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 “(4) A qualified home infusion therapy supplier may
5 subcontract with a pharmacy, physician, provider, or sup-
6 plier to meet the requirements of paragraph (3)(B).”.

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 “(r) PAYMENT FOR HOME INFUSION THERAPY.—

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

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

12 “(3) ANNUAL UPDATES.—The Secretary shall
13 update such schedule from year to year by the per-
14 centage increase in the Consumer Price Index for all
15 urban consumers (United States city average) for
16 the 12-month period ending with June of the pre-
17 ceding year. The Secretary may modify the per diem
18 schedule with respect to beneficiaries who qualify for
19 home infusion therapy services under section
20 1861(iii)(1) but who receive nursing services as
21 home health services.”.

22 (c) CONFORMING AMENDMENTS.—

23 (1) PAYMENT REFERENCE.—Section
24 1833(a)(1) of the Social Security Act (42 U.S.C.
25 1395l(a)(1)) is amended—

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

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

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

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

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

15 (3) EXCLUSION FROM DURABLE MEDICAL
16 EQUIPMENT AND HOME HEALTH SERVICES.—Section
17 1861 of the Social Security Act (42 U.S.C. 1395x)
18 is amended—

19 (A) in subsection (m)(5)—

20 (i) by striking “and” before “durable
21 medical equipment” and inserting a
22 comma; and

23 (ii) by inserting before the semicolon
24 at the end the following: “, and supplies
25 used in the provision of home infusion

1 therapy after excluding other drugs and
 2 biologicals”; and

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

7 (4) APPLICATION OF ACCREDITATION PROVI-
 8 SIONS.—The provisions of section 1865(a) of the So-
 9 cial Security Act (42 U.S.C. 1395bb(a)) apply to the
 10 accreditation of qualified home infusion therapy sup-
 11 pliers in the same way as they apply to other sup-
 12 pliers.

13 **SEC. 3. HOME INFUSION DRUGS.**

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

23 “(C) an infusion drug (as defined in para-
 24 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 or
8 injection, and may include a drug used for catheter
9 maintenance and dec clotting, a drug contained in a
10 device, additives including but not limited to vita-
11 mins, minerals, solutions, and diluents, and other
12 components used in the provision of home infusion
13 therapy.”.

14 **SEC. 4. ENSURING BENEFICIARY ACCESS TO HOME INFU-**
15 **SION THERAPY.**

16 (a) OBJECTIVES IN IMPLEMENTATION.—The Sec-
17 retary of Health and Human Services shall implement the
18 Medicare home infusion therapy benefit under the amend-
19 ments made by this Act in a manner that ensures that
20 Medicare beneficiaries have timely and appropriate access
21 to infusion therapy in their homes and that there is rapid
22 and seamless coordination between drug coverage under
23 part D of title XVIII of the Social Security Act and cov-
24 erage for home infusion therapy services under part B of
25 such title to avoid the filing of duplicative or otherwise

1 improper claims. Specifically, the Secretary shall ensure
2 that—

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

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

15 (3) medical necessity determinations for home
16 infusion therapy will be made—

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

21 (B) in the case of an individual enrolled in
22 a Medicare Advantage plan, by the Medicare
23 Advantage organization offering the plan; and
24 an individual may be initially qualified for cov-

1 erage for such benefit for a 90-day period and
2 subsequent 90-day periods thereafter;

3 (4) except as otherwise provided in this section,
4 the benefit is modeled on current private sector cov-
5 erage and coding for home infusion therapy; and
6 (5) prescription drug plans and MA–PD plans
7 structure their formularies, utilization review proto-
8 cols, and policies in a manner that ensures that
9 Medicare beneficiaries have timely and appropriate
10 access to infusion therapy in their homes.

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

21 **SEC. 5. EFFECTIVE DATE.**

22 The amendments made by this Act shall apply to
23 home infusion therapy furnished on or after January 1,
24 2016.

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