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

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

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.

Be it enacted by the Senate and House of Representa-
tives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Medicare Home Infu-
sion Site of Care Act of 2015”.

SEC. 2. MEDICARE COVERAGE OF HOME INFUSION THER-
APY.

(a) IN GENERAL.—Section 1861 of the Social Secu-

rity Act (42 U.S.C. 1395x) is amended—

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

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

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

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

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

“Home Infusion Therapy

“(iii)(1) The term ‘home infusion therapy’ means the
items and services described in paragraph (2) furnished 
to an individual, who is under the care of a physician,
which are provided by a qualified home infusion therapy 
supplier under a plan (for furnishing such items and serv-
ices to such individual) established and periodically re-
viewed by a physician, which items and services are pro-
vided in an integrated manner in the individual’s home
in conformance with uniform standards of care established 
by the Secretary and in coordination with the provision 
of covered infusion drugs under part D. The Secretary 
shall establish such standards after taking into account 
the standards commonly used for home infusion therapy
by Medicare Advantage plans and in the private sector and after consultation with all interested stakeholders.

“(2) The items and services described in this paragraph are the following:

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

“(B) Other items and services the Secretary determines appropriate to administer infusion drug therapies to an individual safely and effectively in the home.

“(3) For purposes of this subsection:

“(A) The term ‘home’ means a place of residence used as an individual’s home and includes such other alternate settings as the Secretary determines.

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

“(i) has expertise in the preparation of parenteral medications in compliance with enforceable standards of the United States Pharmacopoeia and other nationally recognized standards that regulate preparation of parenteral medications as determined by the Secretary and meets such standards;

“(ii) provides infusion therapy to patients with acute or chronic conditions requiring parenteral administration of drugs and biologicals administered through catheters or needles, or both, in a home; and

“(iii) meets such other uniform requirements as the Secretary determines are necessary to ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour basis (taking into account the standards of care for home infusion therapy established by Medicare Advantage plans and in the private sector), and the efficient administration of the home infusion therapy benefit.
“(4) A qualified home infusion therapy supplier may subcontract with a pharmacy, physician, provider, or supplier to meet the requirements of paragraph (3)(B).”.

(b) PAYMENT FOR HOME INFUSION THERAPY.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

“(r) PAYMENT FOR HOME INFUSION THERAPY.—

“(1) In general.—The Secretary shall determine a per diem schedule for payment for the professional services (including nursing services), supplies, and equipment described in section 1861(iii)(2)(A) for each infusion therapy type that reflects the reasonable costs which must be incurred by efficiently and economically operated qualified home infusion therapy suppliers to provide such services, supplies, and equipment in conformity with applicable State and Federal laws, regulations, and the uniform quality and safety standards developed under section 1861(iii)(1) and to assure that Medicare beneficiaries have reasonable access to such therapy.

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

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

(c) CONFORMING AMENDMENTS.—

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

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

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

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

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

(B) by inserting before the period at the end the following: “, and (I) in the case of home infusion therapy, payment shall be made to the qualified home infusion therapy supplier”.

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

(A) in subsection (m)(5)—

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

(ii) by inserting before the semicolon at the end the following: “, and supplies used in the provision of home infusion therapy after excluding other drugs and biologicals”; and
(B) in subsection (n), by adding at the end the following: “Such term does not include home infusion therapy, other than equipment and supplies used in the provision of insulin.”.

(4) Application of accreditation provisions.—The provisions of section 1865(a) of the Social Security Act (42 U.S.C. 1395bb(a)) apply to the accreditation of qualified home infusion therapy suppliers in the same way as they apply to other suppliers.

SEC. 3. HOME INFUSION DRUGS.

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

(1) in paragraph (1)—

(A) by striking “or” at the end of subparagraph (A);

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

(C) by inserting after subparagraph (B) the following new subparagraph:

“(C) an infusion drug (as defined in paragraph (5)),”; and

(2) by adding at the end the following new paragraph:
“(5) Infusion drug defined.—For purposes of this part, the term ‘infusion drug’ means a parenteral drug or biological administered via an intravenous, intraspinal, intra-arterial, intrathecal, epidural, subcutaneous, or intramuscular access device or injection, and may include a drug used for catheter maintenance and declotting, a drug contained in a device, additives including but not limited to vitamins, minerals, solutions, and diluents, and other components used in the provision of home infusion therapy.”.

SEC. 4. ENSURING BENEFICIARY ACCESS TO HOME INFUSION THERAPY.

(a) Objectives in Implementation.—The Secretary of Health and Human Services shall implement the Medicare home infusion therapy benefit under the amendments made by this Act in a manner that ensures that Medicare beneficiaries have timely and appropriate access to infusion therapy in their homes and that there is rapid and seamless coordination between drug coverage under part D of title XVIII of the Social Security Act and coverage for home infusion therapy services under part B of such title to avoid the filing of duplicative or otherwise improper claims. Specifically, the Secretary shall ensure that—
(1) the benefit is practical and workable with minimal administrative burden for beneficiaries, qualified home infusion therapy suppliers, physicians, prescription drug plans, MA–PD plans, and Medicare Advantage plans, and the Secretary shall consider the use of consolidated claims encompassing covered part D drugs and part B services, supplies, and equipment under such part B to ensure the efficient operation of this benefit;

(2) any prior authorization or utilization review process is expeditious, allowing Medicare beneficiaries meaningful access to home infusion therapy;

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

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

(B) in the case of an individual enrolled in a Medicare Advantage plan, by the Medicare Advantage organization offering the plan; and an individual may be initially qualified for coverage for such benefit for a 90-day period and subsequent 90-day periods thereafter;
(4) except as otherwise provided in this section, the benefit is modeled on current private sector coverage and coding for home infusion therapy; and

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

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

SEC. 5. EFFECTIVE DATE.

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