

110TH  
CONGRESS  
1ST SESSION

# H. R. 2567

To amend title XVIII of the Social Security Act to provide for the coverage of home infusion therapy under the Medicare Program.

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IN THE HOUSE OF REPRESENTATIVES

JUNE 5, 2007

Mr. ENGEL (for himself, Ms. GRANGER, Ms. BALDWIN, Mr. PICKERING, Mr. KUHL of New York, and Mr. TIERNEY) 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 infusion therapy under the Medicare Program.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

### **SECTION 1. SHORT TITLE.**

This Act may be cited as the “Medicare Home Infusion Therapy Coverage Act of 2007”.

### **SEC. 2. MEDICARE COVERAGE OF HOME INFUSION THERAPY.**

(a) **IN GENERAL.**—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended—

(1) in subsection (s)(2)—

- (A) by striking “and” at the end of sub-paragraph (Z);
- (B) by adding “and” at the end of sub-paragraph (AA); and
- (C) by adding at the end the following new subparagraph:

“(BB) home infusion therapy (as defined in subsection (ccc)(1));”; and

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

“Home Infusion Therapy

“(ccc) (1) The term ‘home infusion therapy’ means the following items and services furnished to an individual, who is under the care of a physician, which are provided by a qualified home infusion therapy provider under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician, which items and services are provided in an integrated manner in the individual’s home in conformance with uniform standards of care established by the Secretary (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) and in coordination with the provision of covered infusion drugs under part D:

“(A) Professional services other than nursing services (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, and other items and services the Secretary determines appropriate) to administer infusion drug therapies to an individual safely and effectively in the home.

“(B) Nursing services provided in accordance with the plan, directly by a qualified home infusion therapy provider or under arrangements with an accredited homecare organization, in connection with such infusion, except that such term does not include nursing services to the extent they are covered as home health services;

“(2) For purposes of paragraph (1):

“(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 provider’ means any pharmacy, physician, or other provider licensed by the State in which the pharmacy, physician, or provider resides or provides services, 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 U.S. 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 seven day a week, twenty-four 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.

A qualified home infusion provider may subcontract with a pharmacy, physician, provider, or supplier to meet the requirements of this subsection.

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

“(n) **PAYMENT FOR HOME INFUSION THERAPY.**—The payment amount under this part for home infusion therapy is determined as follows:

“(1) **IN GENERAL.**—The Secretary shall determine a per diem schedule for payment for the professional services, supplies, and equipment described in section 1861(ccc)(1)(A) that reflects the reasonable costs which must be incurred by efficiently and economically operated qualified home infusion therapy providers 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(ccc)(1) and to assure that Medicare beneficiaries have reasonable access to such therapy. The Secretary shall update such schedule from year to year by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year.

“(2) **NURSING SERVICES.**—The Secretary shall develop a methodology for the separate payment for nursing services described in section 1861(ccc)(1)(B) provided in accordance with the plan under such section which reflects the reasonable costs incurred in the provision of nursing services in connection with infusion therapy in conformity with State and Federal laws, regulations, and the uniform quality and safety standards developed pursuant to this Act and to assure that Medicare beneficiaries have reasonable access to nursing services for infusion therapy. The Secretary shall update such schedule from year to year by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending with June of the preceding year.”.

**(c) CONFORMING AMENDMENTS.—**

(1) **PAYMENT REFERENCE.**—Section 1833(a)(1) of the Social Security Act ([42 U.S.C. 13951\(a\)\(1\)](#)) is amended—

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

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

(2) **DIRECT PAYMENT.**—The first sentence of section 1842(b)(6) of such 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 provider”.

**(3) EXCLUSION FROM DURABLE MEDICAL EQUIPMENT AND HOME HEALTH SERVICES.**—Section 1861 of such Act ([42 U.S.C. 1395x](#)) is amended—

(A) in subsection (m), by inserting “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(b) of the Social Security Act ([42 U.S.C. 1395bb\(b\)](#)) apply to the accreditation of qualified home infusion therapy providers in the manner they apply to other suppliers.

### **SEC. 3. MEDICARE COVERAGE OF HOME INFUSION DRUGS.**

**(a) IN GENERAL.**—Section 1860D–2(e)(1) of the Social Security Act ([42 U.S.C. 1395w–102\(e\)\(1\)](#)) 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 (4)),”; and

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

“(4) **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 inserted into the body, and includes a drug used for catheter maintenance and clotting, a drug contained in a device, vitamins, intravenous solutions, diluents and minerals, and other components used in the provision of home infusion therapy.”.

(b) **INFUSION DRUG FORMULARIES.**—For the first 2 years after the effective date of this Act, notwithstanding any other provision of law, prescription drug plans and MA–PD plans under title XVIII of the Social Security Act shall maintain open formularies for infusion drugs (as defined in section 1860D–2(e)(4) of such Act. The Secretary of Health and Human Services shall request the United States Pharmacopeia to develop, in consultation with representatives of qualified home infusion therapy providers and other interested stakeholders, a model formulary approach for home infusion drugs for use by such plans after such 2-year period.

(c) **PART D DISPENSING FEES.**—Section 1860D–2(d)(1)(B) of the Social Security Act ([42 U.S.C. 1395w–102\(d\)\(1\)\(B\)](#)) is amended by inserting after “any dispensing fees for such drugs” the following: “, other than for an infusion drug”.

#### **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. Specifically, the Secretary shall ensure that—

(1) the benefit is practical and workable with minimal administrative burden for beneficiaries, qualified home infusion therapy providers, physicians, prescription drug plans, MA–PD plans, and MA 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 by Medicare administrative contractors under such part B and communicated to the appropriate prescription drug plans and MA–PD plans and an individual may be initially qualified for coverage for such benefit for a 90-day period and subsequent 90-day periods thereafter;

(4) 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) **HOME INFUSION THERAPY ADVISORY PANEL.**—In implementing such home infusion therapy benefit and meeting the objectives specified in subsection (a), the Secretary shall establish an advisory panel comprised of qualified home infusion therapy providers and their representative organizations as well as representatives of the following to provide advice and recommendations:

(1) Patient organizations.

(2) Hospital discharge planners, care coordinators or social workers.

(3) Prescription drug plan sponsors and Medicare Advantage organizations.

(c) **REPORT.**—Not later than January 1, 2010, and every two years thereafter, the Comptroller General of the United States shall submit a report to Congress on Medicare beneficiary access to home infusion therapy. Each such report shall specifically address whether the objectives specified in

subsection (a) have been met and shall make recommendations to Congress and the Secretary 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, 2008.