

112TH CONGRESS  
1ST SESSION

# S. 1203

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 SENATE OF THE UNITED STATES

JUNE 15, 2011

Ms. SNOWE (for herself, Mr. KERRY, Mr. ISAKSON, Ms. KLOBUCHAR, and Mr. INOUE) introduced the following bill; which was read twice and referred to the Committee on Finance

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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.

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 Therapy Coverage Act of 2011”.

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 adding “and” at the end of sub-  
5 paragraph (FF); and

6 (C) by adding at the end the following new  
7 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 following items and services furnished to an individual,  
15 who is under the care of a physician, which are provided  
16 by a qualified home infusion therapy provider under a plan  
17 (for furnishing such items and services to such individual)  
18 established and periodically reviewed by a physician, which  
19 items and services are provided in an integrated manner  
20 in the individual’s home in conformance with uniform  
21 standards of care established by the Secretary (after tak-  
22 ing into account the standards commonly used for home  
23 infusion therapy by Medicare Advantage plans and in the  
24 private sector and after consultation with all interested

1 stakeholders) and in coordination with the provision of  
2 covered infusion drugs under part D:

3           “(A) Professional services other than nursing  
4 services provided in accordance with the plan (in-  
5 cluding administrative, compounding, dispensing,  
6 distribution, clinical monitoring and care coordina-  
7 tion services) and all necessary supplies and equip-  
8 ment (including medical supplies such as sterile tub-  
9 ing and infusion pumps, and other items and serv-  
10 ices the Secretary determines appropriate) to admin-  
11 ister infusion drug therapies to an individual safely  
12 and effectively in the home.

13           “(B) Nursing services provided in accordance  
14 with the plan, directly by a qualified home infusion  
15 therapy provider or under arrangements with an ac-  
16 credited homecare organization, in connection with  
17 such infusion, except that such term does not in-  
18 clude nursing services to the extent they are covered  
19 as home health services.

20           “(2) For purposes of paragraph (1):

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 provider’ 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 U.S. Pharmacopoeia  
10 and other nationally recognized standards that  
11 regulate preparation of parenteral medications  
12 as determined by the Secretary and meets such  
13 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 A qualified home infusion therapy provider may sub-  
5 contract with a pharmacy, physician, provider, or  
6 supplier to meet the requirements of this sub-  
7 section.”.

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

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

15 “(1) IN GENERAL.—The Secretary shall deter-  
16 mine a per diem schedule for payment for the pro-  
17 fessional services, supplies, and equipment described  
18 in section 1861(iii)(1)(A) that reflects the reason-  
19 able costs which must be incurred by efficiently and  
20 economically operated qualified home infusion ther-  
21 apy providers to provide such services, supplies, and  
22 equipment in conformity with applicable State and  
23 Federal laws, regulations, and the uniform stand-  
24 ards of care and other uniform requirements estab-  
25 lished by the Secretary under section 1861(iii) and

1 to assure that Medicare beneficiaries have reason-  
2 able access to such therapy. The Secretary shall up-  
3 date such schedule from year to year by the percent-  
4 age increase in the consumer price index for all  
5 urban consumers (United States city average) for  
6 the 12-month period ending with June of the pre-  
7 ceding year.

8 “(2) NURSING SERVICES.—The Secretary shall  
9 develop a methodology for the separate payment for  
10 nursing services described in section 1861(iii)(1)(B)  
11 provided in accordance with the plan under such sec-  
12 tion which reflects the reasonable costs incurred in  
13 the provision of nursing services in connection with  
14 infusion therapy in conformity with State and Fed-  
15 eral laws, regulations, and the uniform standards of  
16 care and other uniform requirements established by  
17 the Secretary under section 1861(iii) and to assure  
18 that Medicare beneficiaries have reasonable access to  
19 nursing services for infusion therapy. The Secretary  
20 shall update such schedule from year to year by the  
21 percentage increase in the consumer price index for  
22 all urban consumers (United States city average) for  
23 the 12-month period ending with June of the pre-  
24 ceding year.”.

25 (c) CONFORMING AMENDMENTS.—

1           (1)       PAYMENT       REFERENCE.—Section  
2       1833(a)(1) of the Social Security Act (42 U.S.C.  
3       13951(a)(1)) is amended—

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

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

9           (2)       DIRECT PAYMENT.—The first sentence of  
10       section 1842(b)(6) of such Act (42 U.S.C.  
11       1395u(b)(6)) is amended—

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

13                   (B) by inserting before the period at the  
14       end the following: “, and (I) in the case of  
15       home infusion therapy, payment shall be made  
16       to the qualified home infusion therapy pro-  
17       vider”.

18           (3)       EXCLUSION FROM DURABLE MEDICAL  
19       EQUIPMENT AND HOME HEALTH SERVICES.—Section  
20       1861 of such Act (42 U.S.C. 1395x) is amended—

21                   (A) in subsection (m)(5), by inserting “and  
22       supplies 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(b) of the So-  
 7 cial Security Act (42 U.S.C. 1395bb(b)) apply to the  
 8 accreditation of qualified home infusion therapy pro-  
 9 viders in the manner they apply to other suppliers.

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

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

13 (1) in paragraph (1)—

14 (A) by striking “or” at the end of subpara-  
 15 graph (A);

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

18 (C) by inserting before the flush matter  
 19 following subparagraph (B) the following new  
 20 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 in-  
6           serted into the body, and includes a drug used for  
7           catheter maintenance and de clotting, a drug con-  
8           tained in a device, vitamins, intravenous solutions,  
9           diluent and minerals, and other components used in  
10          the provision of home infusion therapy.”.

11          (b) INFUSION DRUG FORMULARIES.—For the first 2  
12         years after the effective date of this Act, notwithstanding  
13         any other provision of law, prescription drug plans and  
14         MA–PD plans under title XVIII of the Social Security Act  
15         shall maintain open formularies for infusion drugs (as de-  
16         fined in section 1860D–2(e)(5) of such Act, as added by  
17         subsection (a)). The Secretary of Health and Human  
18         Services shall request the United States Pharmacopeia to  
19         develop, in consultation with representatives of qualified  
20         home infusion therapy providers and other interested  
21         stakeholders, a model formulary approach for home infu-  
22         sion drugs for use by such plans after such 2-year period.

23          (c) PART D DISPENSING FEES.—Section 1860D–  
24         2(d)(1)(B) of the Social Security Act (42 U.S.C. 1395w–  
25         102(d)(1)(B)) is amended by inserting “, other than for

1 an infusion drug” after “any dispensing fees for such  
2 drugs”.

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

5 (a) OBJECTIVES IN IMPLEMENTATION.—The Sec-  
6 retary shall implement the Medicare home infusion ther-  
7 apy benefit in a manner that ensures that Medicare bene-  
8 ficiaries have timely and appropriate access to home infu-  
9 sion therapy in their homes and that there is rapid and  
10 seamless coordination between drug coverage under part  
11 D of title XVIII of the Social Security Act and coverage  
12 for home infusion therapy under part B of such title. Spe-  
13 cifically, the Secretary shall ensure that—

14 (1) the benefit is practical and workable with  
15 minimal administrative burden for beneficiaries,  
16 qualified home infusion therapy providers, physi-  
17 cians, prescription drug plans, and MA plans (in-  
18 cluding MA–PD plans), and the Secretary shall con-  
19 sider the use of consolidated claims encompassing  
20 covered part D drugs and home infusion therapy to  
21 ensure the efficient operation of this benefit;

22 (2) any prior authorization or utilization review  
23 process under such benefit is expeditious, allowing  
24 Medicare beneficiaries meaningful access to home in-  
25 fusion therapy;

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

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

7           (B) in the case of an individual enrolled in  
8 a Medicare Advantage plan, by the MA organi-  
9 zation offering the plan,

10 and an individual may be initially qualified for cov-  
11 erage for such benefit for a 90-day period and sub-  
12 sequent 90-day periods thereafter;

13           (4) the benefit is modeled on current private  
14 sector coverage and coding for home infusion ther-  
15 apy; and

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

21       (b) HOME INFUSION THERAPY ADVISORY PANEL.—

22 In implementing the Medicare home infusion therapy ben-  
23 efit and meeting the objectives specified in subsection (a),  
24 the Secretary shall establish an advisory panel to provide  
25 advice and recommendations. Such panel shall—

1           (1) be comprised primarily of qualified home in-  
2           fusion therapy providers and their representative or-  
3           ganizations; and

4           (2) include representatives of—

5                   (A) patient organizations;

6                   (B) hospital discharge planners, care coor-  
7           dinators, or social workers; and

8                   (C) PDP sponsors and MA organizations.

9           (c) REPORT.—Not later than January 1, 2014, and  
10          every 2 years thereafter, the Comptroller General shall  
11          submit to Congress and the Secretary a report on Medi-  
12          care beneficiary access to home infusion therapy. Each re-  
13          port submitted under the preceding sentence shall specifi-  
14          cally address whether the objectives specified in subsection  
15          (a) have been met and include recommendations for Con-  
16          gress and the Secretary on how to improve the Medicare  
17          home infusion therapy benefit and better ensure that  
18          Medicare beneficiaries have timely and appropriate access  
19          to infusion therapy in their homes, together with rec-  
20          ommendations for such legislation and administrative ac-  
21          tion as the Comptroller General determines appropriate.

22          (d) DEFINITIONS.—In this section:

23                   (1) COMPTROLLER GENERAL.—The term  
24                   “Comptroller General” means the Comptroller Gen-  
25                   eral of the United States.

1           (2) HOME INFUSION THERAPY.—The term  
2 “home infusion therapy” has the meaning given  
3 such term in section 1861(iii) of the Social Security  
4 Act, as added by section 2(a).

5           (3) MA ORGANIZATION.—The term “MA orga-  
6 nization” has the meaning given such term in sec-  
7 tion 1859(a)(1) of such Act (42 U.S.C. 1395w-  
8 28(a)(1)).

9           (4) MA PLAN.—The term “MA plan” has the  
10 meaning given such term in section 1860D-  
11 1(a)(3)(B) of such Act (42 U.S.C. 1395w-  
12 101(a)(3)(B)).

13           (5) MA-PD PLAN.—The term “MA-PD plan”  
14 has the meaning given such term in section 1860D-  
15 1(a)(3)(C) of such Act (42 U.S.C. 1395w-  
16 101(a)(3)(C)).

17           (6) MEDICARE HOME INFUSION THERAPY BEN-  
18 EFIT.—The term “Medicare home infusion therapy  
19 benefit” means items and services furnished under  
20 the provisions of and amendments made by this Act.

21           (7) PDP SPONSOR.—The term “PDP sponsor”  
22 has the meaning given such term in section 1860D-  
23 41(13) of the Social Security Act (42 U.S.C.  
24 1395w-151(13)).

1           (8) PRESCRIPTION DRUG PLAN.—The term  
2           “prescription drug plan” has the meaning given  
3           such term in section 1860D–41(14) of such Act (42  
4           U.S.C. 1395w–151(14)).

5           (9) QUALIFIED HOME INFUSION THERAPY PRO-  
6           VIDER.—The term “qualified home infusion therapy  
7           provider” has the meaning given such term in para-  
8           graph (2)(B) of such section 1861(iii).

9           (10) SECRETARY.—The term “Secretary”  
10          means the Secretary of Health and Human Services.

11 **SEC. 5. EFFECTIVE DATE.**

12          The provisions of and amendments made by this Act  
13          shall apply to home infusion therapy furnished on or after  
14          January 1, 2012.

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