

108TH CONGRESS
1ST SESSION

H. R. 2476

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

IN THE HOUSE OF REPRESENTATIVES

JUNE 16, 2003

Mr. ENGEL (for himself, Mr. WELDON of Florida, Mr. McNULTY, Mr. FROST, Mr. CASE, and Mr. PAUL) 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 coverage of home infusion drug therapies 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; PURPOSES.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Medicare Home Infusion Therapy Act of 2003”.

6 (b) **PURPOSE.**—The purposes of this Act are to en-
7 sure that medicare beneficiaries—

1 (1) have the choice of receiving infusion drug
2 therapies in the home when clinically appropriate
3 rather than in an inpatient setting; and

4 (2) are receiving high quality, safe, and efficient
5 care with respect to home infusion drug therapies.

6 **SEC. 2. COVERAGE OF AND PAYMENT FOR HOME INFUSION**
7 **DRUG THERAPY SERVICES.**

8 (a) COVERAGE.—

9 (1) IN GENERAL.—Section 1861(s) of the So-
10 cial Security Act (42 U.S.C. 1395x(s)) is amended—

11 (A) in the second sentence, by redesignig-
12 nating paragraphs (16) and (17) as clauses (i)
13 and (ii); and

14 (B) in the first sentence—

15 (i) by striking “and” at the end of
16 paragraph (14);

17 (ii) by striking the period at the end
18 of paragraph (15) and inserting “; and”;
19 and

20 (iii) by adding after paragraph (15)
21 the following new paragraph:

22 “(16) home infusion drug therapy services (as
23 defined in subsection (ww)).”.

24 (2) CONFORMING AMENDMENTS.—Sections
25 1864(a) 1902(a)(9)(C), and 1915(a)(1)(B)(ii)(I) of

1 such Act (42 U.S.C. 1395aa(a), 1396a(a)(9)(C), and
2 1396n(a)(1)(B)(ii)(I)) are each amended by striking
3 “paragraphs (16) and (17)” each place it appears
4 and inserting “clauses (i) and (ii) of the second sen-
5 tence”.

6 (b) HOME INFUSION DRUG THERAPY DEFINED.—
7 Section 1861 of such Act (42 U.S.C. 1395x) is amended
8 by adding at the end the following new subsection:

9 “Home Infusion Drug Therapy Services
10 “(ww)(1) The term ‘home infusion drug therapy serv-
11 ices’ means—

12 “(A) pharmacy, nursing, and related items and
13 services (including medical supplies, intravenous
14 fluids, drugs described in section 1834(n), home de-
15 livery, equipment, and other items and services the
16 Secretary determines appropriate) to administer in-
17 fusion drug therapies to an individual safely and ef-
18 fectively in the home in conformance with clinical
19 standards of care established by the Secretary;

20 “(B) that are furnished by a qualified supplier
21 via an intravenous, intra-arterial or intrathecal ac-
22 cess device inserted into the body; and

23 “(C) provided under a plan of care established
24 and periodically reviewed by a physician.

25 “(2) In paragraph (1)—

1 “(A) the term ‘home’ means a place of resi-
2 dence used as an individual’s home (or a provider of
3 services used as the individual’s home if the drug is
4 administered during a period of inpatient stay for
5 which payment is not made to the provider of serv-
6 ices under part A); and

7 “(B) the term ‘qualified supplier’ means any
8 entity that meets such requirements as the Secretary
9 determines are necessary to ensure the safe and ef-
10 fective provision of home infusion drug therapy serv-
11 ices.”.

12 (c) PAYMENT.—

13 (1) ESTABLISHMENT OF FEE SCHEDULE.—Sec-
14 tion 1834 of the Social Security Act (42 U.S.C.
15 1395l) is amended by adding at the end the fol-
16 lowing new subsection:

17 “(n) HOME INFUSION DRUG THERAPY SERVICES.—

18 “(1) ESTABLISHMENT OF FEE SCHEDULE.—
19 The Secretary shall establish by regulation before
20 the beginning of 2004 and each succeeding year a
21 fee schedule for home infusion drug therapy services
22 for which payment is made under this part. In so
23 doing, the Secretary shall ensure the adequacy of ag-
24 gregate payments for the drug and nondrug compo-

1 nents of home infusion drug therapy, consistent with
2 the requirements of paragraphs (2) and (3).

3 “(2) REQUIREMENTS.—The Secretary shall en-
4 sure that the coverage, reimbursement, and stand-
5 ards for covered home infusion drug therapy services
6 adequately reflect the various components of care
7 (including the services, drugs, supplies, equipment,
8 and related costs) necessary to ensure the safe and
9 effective provision of home infusion drug therapy. In
10 so doing, the Secretary shall—

11 “(A) take into account the definitions, re-
12 quirements, and clinical standards commonly
13 used for home infusion drug therapy by private
14 health plans and accrediting organizations;

15 “(B) ensure the adequacy of the aggregate
16 payment levels for home infusion drug therapy
17 services, without regard to whether payments
18 for drug and nondrug components are bundled
19 or partially bundled by the Secretary;

20 “(C) ensure that sufficient numbers of geo-
21 graphically distributed and qualified home infu-
22 sion drug therapy providers participate in the
23 part B program so that enrolled beneficiaries
24 have meaningful access to home infusion drug

1 therapy services provided in accordance with
2 the established quality of care standards; and

3 “(D) consult with providers and trade as-
4 sociations specializing in home infusion drug
5 therapy.

6 “(3) PUBLICATION OF LIST OF COVERED HOME
7 INFUSION DRUGS.—Not later than January 1, 2004
8 (and quarterly thereafter), the Secretary shall pub-
9 lish a list of the drugs, and indications for such
10 drugs, that are covered home infusion drugs, with
11 respect to which home infusion drug therapy may be
12 provided under this title. This list shall include the
13 following:

14 “(A) All intravenous antibiotic drugs un-
15 less the Secretary has determined for a specific
16 drug and indication that the drug cannot gen-
17 erally be administered safely and effectively in
18 a home setting.

19 “(B) All infusion drug therapies requiring
20 an external infusion pump for safe and effective
21 administration that were, as of June 30, 2003,
22 covered by reason of 1861(s)(6).

23 “(C) Parenterally administered blood-de-
24 rived products.

1 “(D) Any other infusion drug for which
2 the Secretary has determined that, with respect
3 to a specific drug or the indication to which the
4 drug is applied, the drug can be administered
5 safely and effectively in the home (as defined in
6 section 1861(w)(2)(A)).”.

7 (2) CONFORMING AMENDMENTS.—(A) Section
8 1833(a)(1) of such Act (42 U.S.C. 1395l(1)) is
9 amended—

10 (i) by striking “and (U)” and inserting
11 “(U)”; and

12 (ii) by inserting before the semicolon at the
13 end the following: “, and (V) with respect to
14 home infusion drug therapy services (as defined
15 in section 1861(w)(1)), the amounts paid shall
16 be 80 percent of the lesser of the actual charge
17 or the amount determined under the fee sched-
18 ule established under section 1834(n)”.

19 (B) The first sentence of section 1862(a) of
20 such Act (42 U.S.C. 1395y(a)) is amended—

21 (i) by striking “or” at the end of para-
22 graph (20);

23 (ii) by striking the period at the end of
24 paragraph (21) and inserting “; or”; and

1 (iii) by inserting after paragraph (21) the
2 following new paragraph:

3 “(22) in the case of home infusion drug therapy
4 services under section 1861(ww)—

5 “(A) that are not furnished in the home
6 (as defined in paragraph (2)(A) of that sec-
7 tion);

8 “(B) that do not meet the standards of
9 clinical care established by the Secretary;

10 “(C) that include drugs not listed under
11 section 1834(n)(3);

12 “(D) that are items and services other
13 than items and services that the Secretary de-
14 termines appropriate under that section; and

15 “(E) for which payment may be made
16 under this title other than under section
17 1833(a)(1)(V).”.

18 (d) EXCLUSION FROM DEFINITION OF DURABLE
19 MEDICAL EQUIPMENT.—Section 1861(n) of such Act (42
20 U.S.C. 1395x(n)) is amended by adding at the end the
21 following: “Such term does not include home infusion drug
22 therapy services (as defined in subsection (ww)).”.

23 (e) EFFECTIVE DATE.—The amendments made by
24 this section shall apply to items and services furnished on
25 or after January 1, 2004. The Secretary shall publish a

1 rule under this subsection in the Federal Register by not
2 later than January 1, 2004. Such rule shall be effective
3 and final immediately on an interim basis, but is subject
4 to change and revision after public notice and opportunity
5 for a period (of not less than 60 days) for public comment.

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