

107TH CONGRESS  
1ST SESSION

# H. R. 2750

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

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## IN THE HOUSE OF REPRESENTATIVES

AUGUST 2, 2001

Mr. ENGEL (for himself, Ms. HART, Mr. TOWNS, and Mr. RUSH) 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 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 2001”.

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 redesign-  
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), as amended  
8       by sections 102 and 105 of the Medicare, Medicaid, and  
9       SCHIP Benefits Improvement and Protection Act of 2000  
10      (114 Stat. 2763A–468, 471), as enacted into law by sec-  
11      tion 1(a)(6) of Public Law 106–554, is amended by add-  
12      ing at the end the following new subsection:

13             “Home Infusion Drug Therapy Services  
14             “(ww)(1) The term ‘home infusion drug therapy serv-  
15             ices’ means—

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

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

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

6 “(2) In paragraph (1)—

7 “(A) the term ‘home’ means a place of resi-  
 8 dence used as an individual’s home (or a provider of  
 9 services used as the individual’s home if the drug is  
 10 administered during a period of inpatient stay for  
 11 which payment is not made to the provider of serv-  
 12 ices under part A); and

13 “(B) the term ‘qualified supplier’ means any  
 14 entity that meets such requirements as the Secretary  
 15 determines are necessary to ensure the safe and ef-  
 16 fective provision of home infusion drug therapy serv-  
 17 ices.”.

18 (c) PAYMENT.—

19 (1) ESTABLISHMENT OF FEE SCHEDULE.—Sec-  
 20 tion 1834 of the Social Security Act (42 U.S.C.  
 21 1395l), as amended by section 223(b) of the Medi-  
 22 care, Medicaid, and SCHIP Benefits Improvement  
 23 and Protection Act of 2000 (114 Stat. 2763A–487),  
 24 as enacted into law by section 1(a)(6) of Public Law

1 106–554, is amended by adding at the end the fol-  
2 lowing new subsection:

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

4 “(1) ESTABLISHMENT OF FEE SCHEDULE.—

5 The Secretary shall establish by regulation before  
6 the beginning of 2002 and each succeeding year a  
7 fee schedule for home infusion drug therapy services  
8 for which payment is made under this part. In so  
9 doing, the Secretary shall ensure the adequacy of ag-  
10 gregate payments for the drug and nondrug compo-  
11 nents of home infusion drug therapy, consistent with  
12 the requirements of paragraphs (2) and (3).

13 “(2) REQUIREMENTS.—The Secretary shall en-  
14 sure that the coverage, reimbursement, and stand-  
15 ards for covered home infusion drug therapy services  
16 adequately reflect the various components of care  
17 (including the services, drugs, supplies, equipment,  
18 and related costs) necessary to ensure the safe and  
19 effective provision of home infusion drug therapy. In  
20 so doing, the Secretary shall—

21 “(A) take into account the definitions, re-  
22 quirements, and clinical standards commonly  
23 used for home infusion drug therapy by private  
24 health plans and accrediting organizations;

1           “(B) ensure the adequacy of the aggregate  
2           payment levels for home infusion drug therapy  
3           services, without regard to whether payments  
4           for drug and nondrug components are bundled  
5           or partially bundled by the Secretary;

6           “(C) ensure that sufficient numbers of geo-  
7           graphically distributed and qualified home infu-  
8           sion drug therapy providers participate in the  
9           part B program so that enrolled beneficiaries  
10          have meaningful access to home infusion drug  
11          therapy services provided in accordance with  
12          the established quality of care standards; and

13          “(D) consult with providers and trade as-  
14          sociations specializing in home infusion drug  
15          therapy.

16          “(3) PUBLICATION OF LIST OF COVERED HOME  
17          INFUSION DRUGS.—Not later than January 1, 2002  
18          (and quarterly thereafter), the Secretary shall pub-  
19          lish a list of the drugs, and indications for such  
20          drugs, that are covered home infusion drugs, with  
21          respect to which home infusion drug therapy may be  
22          provided under this title. This list shall include the  
23          following:

24                 “(A) All intravenous antibiotic drugs un-  
25                 less the Secretary has determined for a specific

1 drug and indication that the drug cannot gen-  
2 erally be administered safely and effectively in  
3 a home setting.

4 “(B) All infusion drug therapies requiring  
5 an external infusion pump for safe and effective  
6 administration that were, as of June 30, 2001,  
7 covered by reason of 1861(s)(6).

8 “(C) Parenterally administered blood-de-  
9 rived products.

10 “(D) Any other infusion drug for which  
11 the Secretary has determined that, with respect  
12 to a specific drug or the indication to which the  
13 drug is applied, the drug can be administered  
14 safely and effectively in the home (as defined in  
15 section 1861(w)(2)(A)).”.

16 (2) CONFORMING AMENDMENTS.—(A) Section  
17 1833(a)(1) of such Act (42 U.S.C. 1395l(1)), as  
18 amended by sections 105(c) and 223(c) of the Medi-  
19 care, Medicaid, and SCHIP Benefits Improvement  
20 and Protection Act of 2000 (114 Stat. 2763A–  
21 YYY472, 489), as enacted into law by section  
22 1(a)(6) of Public Law 106–554, is amended—

23 (i) by striking “and (U)” and inserting  
24 “(U)”; and

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

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

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

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

14 (iii) by inserting after paragraph (21) the  
15 following new paragraph:

16 “(22) in the case of home infusion drug therapy  
17 services under section 1861(w)—

18 “(A) that are not furnished in the home  
19 (as defined in paragraph (2)(A) of that section;

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

22 “(C) that include drugs not listed under  
23 section 1834(n)(3);



1           “(D) that are items and services other  
 2           than items and services that Secretary deter-  
 3           mines appropriate under that section; and

4           “(E) for which payment may be made  
 5           under this title other than under section  
 6           1833(a)(1)(V).”.

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

12          (e) EFFECTIVE DATE.—The amendments made by  
 13 this section shall apply to items and services furnished on  
 14 or after January 1, 2002. The Secretary shall publish a  
 15 rule under this subsection in the Federal Register by not  
 16 later than the January 1, 2002. Such rule shall be effec-  
 17 tive and final immediately on an interim basis, but is sub-  
 18 ject to change and revision after public notice and oppor-  
 19 tunity for a period (of not less than 60 days) for public  
 20 comment.

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