

103D CONGRESS  
1ST SESSION

# S. 516

To amend title XVIII of the Social Security Act to improve procedures under part B of the medicare program relating to durable medical equipment, and for other purposes.

---

## IN THE SENATE OF THE UNITED STATES

MARCH 5 (legislative day, MARCH 3), 1993

Mr. PRYOR (for himself, Mr. SASSER, Mr. COHEN, Mr. GRASSLEY, Mr. CONRAD, Mr. DURENBERGER, Mr. LEAHY, and Mr. McCAIN) 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 improve procedures under part B of the medicare program relating to durable medical equipment, and for other purposes.

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. REFERENCES TO SOCIAL SECURITY ACT.**

4       Except as otherwise specifically provided, whenever in  
5       this Act an amendment is expressed in terms of an amend-  
6       ment to or repeal of a section or other provision, the ref-

1 erence shall be considered to be made to that section or  
2 other provision of the Social Security Act.

3 **SEC. 2. DURABLE MEDICAL EQUIPMENT.**

4 (a) DEFINITION OF MEDICAL EQUIPMENT AND SUP-  
5 PLIES.—

6 (1) IN GENERAL.—Section 1861 (42 U.S.C.  
7 1395x) is amended by adding at the end the follow-  
8 ing new subsection:

9 “MEDICAL EQUIPMENT AND SUPPLIES

10 “(oo) The term ‘medical equipment and supplies’  
11 means—

12 “(1) durable medical equipment (as defined in  
13 section 1861(n));

14 “(2) prosthetic devices (as described in section  
15 1861(s)(8));

16 “(3) orthotics and prosthetics (as described in  
17 section 1861(s)(9));

18 “(4) home dialysis supplies and equipment (as  
19 described in section 1861(s)(2)(F));

20 “(5) surgical dressings and other devices (as  
21 described in section 1861(s)(5));

22 “(6) immunosuppressive drugs (as described in  
23 section 1861(s)(2)(J)); and

24 “(7) such other items as the Secretary may de-  
25 termine.”.

4 (b) DEVELOPMENT AND APPLICATION OF NATIONAL  
5 STANDARDS FOR SUPPLIERS OF MEDICAL EQUIPMENT  
6 AND SUPPLIES.—Section 1834 (42 U.S.C. 1395m) is  
7 amended by adding at the end the following new sub-  
8 section:

9        "(i) REQUIREMENTS FOR ISSUANCE AND RENEWAL  
10 OF SUPPLIER NUMBERS FOR SUPPLIERS OF MEDICAL  
11 EQUIPMENT AND SUPPLIES.—

12           “(1) PAYMENT.—No payment may be made  
13        under this part after July 1, 1994, for items fur-  
14        nished by a supplier of medical equipment and sup-  
15        plies (as defined in section 1861(oo)) unless such  
16        supplier meets the national standards specified by  
17        the Secretary and possesses a valid supplier number.

18                   “(2) REVISED STANDARDS.—

19                         “(A) IN GENERAL.—The Secretary shall,  
20                         by no later than January 1, 1996, in consulta-  
21                         tion with representatives of suppliers of medical  
22                         equipment and supplies, carriers, and consum-  
23                         ers, revise the national standards for suppliers  
24                         of medical equipment and supplies to include  
25                         the requirements listed in subparagraph (B).

1                   “(B) STANDARDS DESCRIBED.—The re-  
2                   quirements listed in this subparagraph are that  
3                   suppliers of medical equipment and supplies  
4                   shall—

5                   “(i) comply with all applicable State  
6                   and Federal licensure and regulatory re-  
7                   quirements;

8                   “(ii) maintain a physical facility on an  
9                   appropriate site;

10                   “(iii) have proof of appropriate liabil-  
11                   ity insurance; and

12                   “(iv) meet such other requirements as  
13                   the Secretary may specify.

14                   “(C) APPLICABILITY OF REVISED STAND-  
15                   ARDS.—Beginning after December 31, 1995,  
16                   each supplier of medical equipment and supplies  
17                   applying for a supplier number or renewing  
18                   such supplier's supplier number shall meet the  
19                   revised standards described in this paragraph.”.

20                   (c) CERTIFICATES OF MEDICAL NECESSITY.—

21                   (1) IN GENERAL.—Section 1834 (42 U.S.C.  
22                   1395m), as amended by subsection (b), is amend-  
23                   ed—

24                   (A) in subsection (a), by striking para-  
25                   graph (16), and

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

3        "(j) CERTIFICATES OF MEDICAL NECESSITY.—

4           “(1) STANDARDIZED CERTIFICATES.—Not later  
5           than July 1, 1994, the Secretary shall, in consulta-  
6           tion with carriers under this part, develop one or  
7           more standardized certificates of medical necessity  
8           (as defined in paragraph (3)) for medical equipment  
9           and supplies (as defined in section 1861(oo) other  
10           than paragraphs (4), (6), and (7)). If a certificate  
11           of medical necessity is required by the Secretary,  
12           such standardized certificates shall—

16                   “(B) be transmitted to the supplier and  
17                   then to the carrier processing the claim for pay-  
18                   ment for such medical equipment and supplies  
19                   under this part.

20               “(2) PROHIBITION AGAINST DISTRIBUTION BY  
21               SUPPLIERS OF CERTIFICATES OF MEDICAL NECES-  
22               SITY.—

23                   “(A) IN GENERAL.—Except as provided in  
24                   subparagraph (B), a supplier of medical equip-  
25                   ment and supplies described in paragraph (1)

1 may not distribute to physicians or to individuals  
2 entitled to benefits under this part for  
3 commercial purposes any completed or partially  
4 completed certificates of medical necessity.

5           “(B) EXCEPTION FOR CERTAIN BILLING  
6 INFORMATION.—Subparagraph (A) shall not  
7 apply with respect to a certificate of medical ne-  
8 cessity to the extent that such certificate con-  
9 tains only information completed by the sup-  
10 plier of medical equipment and supplies identi-  
11 fying such supplier and the beneficiary to whom  
12 such medical equipment and supplies are fur-  
13 nished, a description of such medical equipment  
14 and supplies, any product code identifying such  
15 medical equipment and supplies, and any other  
16 administrative information identified by the  
17 Secretary. In the event a supplier provides a  
18 certificate of medical necessity containing infor-  
19 mation permitted under this subparagraph,  
20 such certificate shall also contain the supplier’s  
21 charge and the fee schedule amount for the  
22 medical equipment or supplies being furnished  
23 prior to distribution of such certificate to the  
24 physician.

1                   “(C) PENALTY.—Any supplier of medical  
2                   equipment and supplies who knowingly and will-  
3                   fully distributes a certificate of medical neces-  
4                   sity in violation of subparagraph (A) is subject  
5                   to a civil money penalty in an amount not to  
6                   exceed \$1,000 for each such certificate of medi-  
7                   cal necessity so distributed. The provisions of  
8                   section 1128A (other than subsections (a) and  
9                   (b)) shall apply to civil money penalties under  
10                   this subparagraph in the same manner as they  
11                   apply to a penalty or proceeding under section  
12                   1128A(a).

13                   “(3) DEFINITION.—For purposes of this sub-  
14                   section, the term ‘certificate of medical necessity’  
15                   means a form or other document containing infor-  
16                   mation required by the Secretary to be submitted to  
17                   show that a covered item is reasonable and nec-  
18                   essary for the diagnosis or treatment of illness or in-  
19                   jury or to improve the functioning of a malformed  
20                   body member.”.

21                   (2) EFFECTIVE DATE.—The amendments made  
22                   by paragraph (1) shall apply with respect to certifi-  
23                   cates of medical necessity on or after January 1,  
24                   1994.

1       (d) COVERAGE AND REVIEW CRITERIA FOR CERTAIN  
2 MEDICAL EQUIPMENT AND SUPPLIES.—Section 1834 (42  
3 U.S.C. 1395m), as amended by subsection (c), is amended  
4 by adding at the end the following new subsection:

5       “(k) COVERAGE AND REVIEW CRITERIA.—

6       “(1) DEVELOPMENT AND ESTABLISHMENT.—  
7       Not later than July 1, 1994, the Secretary, in con-  
8       sultation with representatives of suppliers of medical  
9       equipment and supplies (as defined in section  
10      1861(oo) other than paragraphs (4), (6), and (7)),  
11      individuals enrolled under this part, and appropriate  
12      medical specialty societies, shall develop and estab-  
13      lish uniform national coverage and utilization review  
14      criteria for 200 items of medical equipment and sup-  
15      plies (as so defined) selected in accordance with the  
16      standards described in paragraph (2). The Secretary  
17      shall publish the criteria as part of the instructions  
18      provided to fiscal intermediaries and carriers under  
19      this part and no further publication, including publi-  
20      cation in the Federal Register, shall be required.

21       “(2) STANDARDS FOR SELECTING ITEMS SUB-  
22      JECT TO CRITERIA.—The Secretary may select an  
23      item for coverage under the criteria developed and  
24      established under paragraph (1) if the Secretary  
25      finds that—

1                   “(A) the item is frequently purchased or  
2                   rented by beneficiaries;

3                   “(B) the item is frequently subject to a de-  
4                   termination that such item is not medically nec-  
5                   essary; or

6                   “(C) the coverage or utilization criteria ap-  
7                   plied to the item (as of the date of the enact-  
8                   ment of this subsection) is not consistent  
9                   among carriers.

10                  “(3) ANNUAL REVIEW AND EXPANSION OF  
11                  ITEMS SUBJECT TO CRITERIA.—The Secretary shall  
12                  annually review the coverage and utilization of items  
13                  of medical equipment and supplies to determine  
14                  whether items not included among the items selected  
15                  under paragraph (1) should be made subject to uni-  
16                  form national coverage and utilization review cri-  
17                  teria, and, if appropriate, shall develop and apply  
18                  such criteria to such additional items.

19                  “(4) REPORT ON EFFECT OF UNIFORM CRI-  
20                  TERIA ON UTILIZATION OF ITEMS.—Not later than  
21                  January 1, 1995, the Secretary shall submit a re-  
22                  port to the Committee on Ways and Means and the  
23                  Committee on Energy and Commerce of the House  
24                  of Representatives and the Committee on Finance of  
25                  the Senate analyzing the impact of the uniform cri-

1       teria established under paragraph (1) on the utilization  
2       of items of medical equipment and supplies by  
3       individuals enrolled under this part.”.

4       (e) PROHIBITION AGAINST MULTIPLE SUPPLIER  
5       NUMBERS.—

6               (1) IN GENERAL.—Section 1834 (42 U.S.C.  
7               1395m), as amended by subsection (d), is amended  
8               by adding at the end the following new subsection:  
9               “(l) PROHIBITION AGAINST MULTIPLE SUPPLIER  
10       NUMBERS FOR SUPPLIERS OF MEDICAL EQUIPMENT AND  
11       SUPPLIES.—The Secretary may not issue more than one  
12       supplier number to any supplier of medical equipment and  
13       supplies (as defined in section 1861(oo)) unless the issuance  
14       of more than one number is appropriate to identify  
15       subsidiary or regional entities under the supplier’s ownership  
16       or control.”.

17               (2) EFFECTIVE DATE.—The amendment made  
18       by paragraph (1) shall apply to items furnished on  
19       or after July 1, 1994.

20       (f) DEFINITION OF INDUCEMENTS AS KICKBACKS  
21       CLARIFIED.—

22               (1) IN GENERAL.—Section 1128B(b)(3)(B) (42  
23       U.S.C. 1320a-7b(b)(3)(B)) is amended by inserting  
24       before the semicolon “(except that in the case of a  
25       contract supply arrangement between a skilled nurs-

1       ing facility and a supplier of medical supplies and  
2       equipment (as defined in section 1861(oo) other  
3       than paragraphs (4), (6), and (7)), such employment  
4       shall not be considered bona fide to the extent that  
5       it includes tasks of a clerical and cataloging nature  
6       in transmitting to suppliers assignment rights of in-  
7       dividuals eligible for benefits under part B of title  
8       XVIII, or performance of warehousing or stock in-  
9       ventory functions)’’.

13 (g) LIMITATION ON BENEFICIARY LIABILITY.—

14 (1) IN GENERAL.—Section 1879 (42 U.S.C.  
15 1395pp) is amended by adding at the end the follow-  
16 ing new subsection:

17        “(h) If a supplier of medical equipment and supplies  
18 (as defined in section 1861(oo))—

19               “(1) furnishes an item or service to a bene-  
20               ficiary for which no payment may be made by reason  
21               of section 1834(i);

22               “(2) furnishes an item or service to a bene-  
23               ficiary for which payment is denied in advance under  
24               section 1834(a)(15);

1               “(3) is excluded from participation under this  
2 title; or

3               “(4) furnishes an item or service to a bene-  
4 ficiary for which payment is denied under section  
5 1862(a)(1);

6 any expenses incurred for items and services furnished to  
7 an individual by such a supplier on an unassigned basis  
8 shall be the responsibility of such supplier. The individual  
9 shall have no financial responsibility for such expenses and  
10 the supplier shall refund on a timely basis to the individual  
11 (and shall be liable to the individual for) any amounts col-  
12 lected from the individual for such items or services, un-  
13 less the supplier informs the individual in advance that  
14 payment under this part will not be made for the item  
15 or services and the individual agrees to pay for the item  
16 or service.”.

17               (2) EFFECTIVE DATE.—The amendment made  
18 by paragraph (1) shall apply to items or services  
19 furnished on or after July 1, 1994.

20               (h) TREATMENT OF NEBULIZERS AND ASPIRATORS  
21 AS MISCELLANEOUS ITEMS OF DURABLE MEDICAL  
22 EQUIPMENT.—

23               (1) IN GENERAL.—Section 1834(a)(3)(A) (42  
24 U.S.C. 1395m(a)(3)(A)) is amended by striking  
25 “ventilators, aspirators, IPPB machines, and

1       nebulizers" and inserting "ventilators and IPPB ma-  
2       chines".

3                   (2) PAYMENT FOR SUPPLIES RELATING TO  
4       NEBULIZERS        AND       ASPIRATORS.—Section  
5       1834(a)(7)(A) (42 U.S.C. 1395m(a)(7)(A)) is  
6       amended by striking "and" at the end of clause (v),  
7       by striking the period at the end of clause (vi) and  
8       inserting ";" and", and by inserting after clause (vi)  
9       the following new clause:

10                   "(vii) In the case of supplies to be  
11       used in conjunction with a nebulizer or as-  
12       pirator for which payment is made under  
13       this paragraph, payment shall be in ac-  
14       cordance with paragraph (2) of this sub-  
15       section.".

16                   (3) EFFECTIVE DATE.—The amendments made  
17       by this subsection shall apply to items furnished on  
18       or after January 1, 1994.

19                   (i) PAYMENT FOR OSTOMY SUPPLIES, TRACHE-  
20       OSTOMY SUPPLIES, UROLOGICALS, SURGICAL DRESSINGS,  
21       AND OTHER MEDICAL SUPPLIES.—

22                   (1) IN GENERAL.—Section 1834(h)(1) (42  
23       U.S.C. 1395m(h)(1)) is amended by adding at the  
24       end the following new subparagraph:

1               “(E) EXCEPTION FOR CERTAIN ITEMS.—  
2               Payment for ostomy supplies, tracheostomy  
3               supplies, urologicals, surgical dressings, and  
4               other medical supplies shall be made in accord-  
5               ance with subparagraphs (B) and (C) of section  
6               1834(a)(2) (except that in the case of surgical  
7               dressings, the national limited payment amount  
8               shall be computed based on local payment  
9               amounts using average reasonable charges for  
10               the six-month period ending June 30, 1993, in-  
11               creased by the covered item update for 1994).”.

12               (2) EFFECTIVE DATES.—

13               (A) IN GENERAL.—Except as provided in  
14               subparagraph (B), the amendment made by  
15               paragraph (1) shall apply with respect to items  
16               furnished on or after January 1, 1994.

17               (B) SURGICAL DRESSINGS AND OTHER  
18               MEDICAL SUPPLIES.—The amendment made by  
19               paragraph (1) with respect to surgical dressings  
20               and other medical supplies shall apply to items  
21               supplied on or after July 1, 1994.

22               (j) FREEZE IN REASONABLE CHARGES FOR PAREN-  
23               TERAL AND ENTERAL NUTRIENTS, SUPPLIES, AND  
24               EQUIPMENT DURING 1994.—In determining the amount  
25               of payment under part B of title XVIII of the Social Secu-

1 rity Act during 1994, the charges determined to be rea-  
2 sonable with respect to parenteral and enteral nutrients,  
3 supplies, and equipment may not exceed the charges deter-  
4 mined to be reasonable with respect to such nutrients,  
5 supplies, and equipment during 1993.

6 (k) STUDIES.—

7 (1) SUPPLIES AND SERVICES IN NURSING FA-  
8 CILITIES.—The Comptroller General of the United  
9 States shall conduct a study and report to the Con-  
10 gress no later than January 1, 1995, on the types,  
11 volume, and utilization of services and supplies fur-  
12 nished under contract or under arrangement with  
13 suppliers to individuals eligible for benefits under  
14 title XVIII of the Social Security Act residing in  
15 skilled nursing facilities and nursing facilities.

16 (2) DESCRIPTIONS RELATING TO CERTAIN  
17 CODES.—The Comptroller General of the United  
18 States shall conduct a study beginning no earlier  
19 than July 1, 1994, and report to the Congress no  
20 later than January 1, 1995, on—

21 (A) whether changes made by the Depart-  
22 ment of Health and Human Services to the de-  
23 scriptions relating to the codes for medical  
24 equipment and supplies (as defined in section

1           1861(oo) of the Social Security Act other than  
2           paragraphs (4), (6), and (7)—

5 (ii) are sufficiently explicit to distin-  
6 guish between items of varying quality and  
7 price, and

8 (B) recommendations for additional  
9 changes that would improve the descriptions re-  
10 lating to the codes for such items.

○

S 516 IS—2