

103^D 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.”.

1 (2) EFFECTIVE DATE.—The amendment made
2 by paragraph (1) shall apply to items furnished on
3 or after January 1, 1994.

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 requirements 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(o)) 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—

13 “(A) be completed by each physician who
14 prescribes such medical equipment and supplies
15 for any beneficiary under this part, and

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 individ-
2 uals 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(o) 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 utiliza-
2 tion 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 issu-
14 ance of more than one number is appropriate to identify
15 subsidiary or regional entities under the supplier’s owner-
16 ship 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(o)) 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)”.
10

11 (2) EFFECTIVE DATE.—The amendment made
12 by paragraph (1) shall apply with respect to services
13 furnished on or after January 1, 1994.

14 (g) LIMITATION ON BENEFICIARY LIABILITY.—

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

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

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

23 “(2) furnishes an item or service to a bene-
24 ficiary for which payment is denied in advance under
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(o) of the Social Security Act other than
2 paragraphs (4), (6), and (7))—

3 (i) accurately reflect the items being
4 furnished under such codes, and

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.

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S 516 IS—2