

108TH CONGRESS
1ST SESSION

S. 1303

To amend title XVIII of the Social Security Act and otherwise revise the Medicare Program to reform the method of paying for covered drugs, drug administration services, and chemotherapy support services.

IN THE SENATE OF THE UNITED STATES

JUNE 20, 2003

Mr. BROWNBACK (for himself, Mr. NELSON of Florida, and Mr. NICKLES) 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 and otherwise revise the Medicare Program to reform the method of paying for covered drugs, drug administration services, and chemotherapy support services.

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 “Quality Cancer Care
5 Preservation Act”.

1 **SEC. 2. MEDICARE PAYMENT FOR DRUGS AND**
 2 **BIOLOGICALS.**

3 (a) IN GENERAL.—Section 1842(o)(1) of the Social
 4 Security Act (42 U.S.C. 1395u(o)(1)) is amended by strik-
 5 ing “95 percent of the average wholesale price” and insert-
 6 ing “the payment amount specified in section
 7 1834(n)(2)”.

8 (b) DETERMINATION OF PAYMENT AMOUNT.—Sec-
 9 tion 1834 of such Act (42 U.S.C. 1395m) is amended by
 10 adding at the end the following new subsection:

11 “(n) PAYMENT FOR DRUGS AND BIOLOGICALS.—

12 “(1) REPORTS BY MANUFACTURERS.—

13 “(A) IN GENERAL.—Every drug manufac-
 14 turer shall report to the Secretary, in the man-
 15 ner prescribed in this paragraph, its average
 16 sales price (as defined in subparagraph (B)) in
 17 the United States during each calendar quarter
 18 for drugs and biologicals covered under this
 19 part.

20 “(B) DEFINITIONS.—For purposes of this
 21 subsection—

22 “(i) the term ‘manufacturer’ means,
 23 with respect to a drug or biological, the en-
 24 tity identified by the Labeler Code portion
 25 of the National Drug Code of such drug or
 26 biological; and

1 “(ii) the term ‘average sales price’
2 means the weighted average of all final
3 sales prices to all purchasers, excluding
4 sales specified in subparagraph (C).

5 In determining such average sales prices, such
6 prices shall be net of volume discounts,
7 chargebacks, short-dated product discounts,
8 free goods contingent on purchases, rebates
9 (other than those made or authorized under
10 section 1927), and all other price concessions
11 that result in a reduction of the ultimate cost
12 to the purchaser.

13 “(C) CONSIDERATION IN CALCULATION OF
14 AVERAGE SALES PRICES.—The calculation of
15 average sales price under this subsection shall
16 not include—

17 “(i) prices that are excluded from the
18 calculation of ‘best price’ under section
19 1927(c)(1)(C);

20 “(ii) prices offered to entities that are
21 considered under subparagraph (B)(i) to
22 be the manufacturers of the drugs or
23 biologicals involved;

1 “(iii) prices offered by a manufacturer
2 to a hospital, nursing facility, hospice, or
3 health maintenance organization;

4 “(iv) prices to governmental entities;
5 and

6 “(v) nominal prices offered to bona
7 fide charitable organizations.

8 “(D) QUARTERLY REPORTS.—Each manu-
9 facturer shall submit the report required by
10 subparagraph (A) to the Secretary by electronic
11 means no later than 30 days after the end of
12 a calendar quarter with respect to sales that oc-
13 curred during such quarter. The Secretary shall
14 prescribe the format and other requirements for
15 the report.

16 “(E) ENFORCEMENT.—

17 “(i) FAILURE TO TIMELY REPORT.—
18 The Secretary may impose a civil monetary
19 penalty in an amount not to exceed
20 \$100,000 on a manufacturer that fails to
21 provide the information required under this
22 paragraph on a timely basis and in the
23 manner required.

24 “(ii) FALSE INFORMATION.—For each
25 item of false information, the Secretary

1 may impose a civil money penalty in an
2 amount not to exceed \$100,000 on a man-
3 ufacturer that knowingly provides false in-
4 formation under this paragraph.

5 “(iii) MANNER OF IMPOSITION OF
6 CIVIL MONETARY PENALTIES.—The provi-
7 sions in section 1128A (other than sub-
8 sections (a) and (b)) shall apply to a civil
9 monetary penalty under this subparagraph
10 in the same manner as such provisions
11 apply to a penalty or proceeding under sec-
12 tion 1128A(a).

13 “(F) CONFIDENTIALITY OF INFORMA-
14 TION.—Notwithstanding any other provision of
15 law, information disclosed by manufacturers
16 under this paragraph is confidential and shall
17 not be disclosed by the Secretary in any form
18 other than as specifically authorized by this
19 subsection.

20 “(2) CALCULATION OF PAYMENT AMOUNT.—

21 “(A) IN GENERAL.—Except as otherwise
22 provided in this paragraph, the payment
23 amount for a drug or biological furnished dur-
24 ing a calendar quarter shall be 120 percent of
25 the average sales price of the drug or biological

1 for the second preceding calendar quarter as
2 determined under paragraph (1).

3 “(B) METHODOLOGY.—In determining
4 payment amounts under subparagraph (A), the
5 Secretary may, in the Secretary’s discretion,
6 use either the average sales price for each drug
7 or biological by specific drug or biological, or a
8 cumulative average sales price based on sales
9 data for all versions of a multiple-source drug
10 that the Secretary, acting through the Food
11 and Drug Administration, has determined are
12 therapeutically equivalent (as evidenced by ‘A’
13 ratings in the publication Approved Drug Prod-
14 ucts with Therapeutic Equivalence Evalua-
15 tions).

16 “(C) INCREASE TO REFLECT ADDITIONAL
17 COSTS ATTRIBUTABLE TO STATE AND LOCAL
18 TAXES.—In the case of a drug or biological that
19 was subject to a State or local sales tax or
20 gross receipts tax when administered or dis-
21 pensed, the payment amount determined under
22 subparagraph (A) shall be increased by the
23 amount of such tax paid with respect to such
24 drug or biological.

1 “(D) SUBSTITUTION OF HIGHER PAYMENT
2 AMOUNT.—If a physician’s, supplier’s, or any
3 other person’s claim for payment for services
4 under this Act documents that the price paid
5 for a drug or biological was greater than the
6 payment amount determined under subpara-
7 graph (A), the actual amount paid shall be sub-
8 stituted for the payment amount determined
9 under subparagraph (A), unless the Secretary
10 determines that the actual amount paid was un-
11 reasonable under the circumstances.

12 “(E) INCREASE FOR BAD DEBT AND CER-
13 TAIN OTHER COSTS.—Upon the submission of
14 supporting information, the Secretary shall
15 make an additional payment to a physician or
16 supplier to cover—

17 “(i) uncollectible deductibles and coin-
18 surance due from Medicare beneficiaries
19 with respect to drugs and biologicals fur-
20 nished to such beneficiaries; and

21 “(ii) costs incurred in procuring and
22 billing for drugs and biologicals furnished
23 to Medicare beneficiaries.”.

1 **SEC. 3. MEDICARE PAYMENT FOR DRUG ADMINISTRATION**
2 **SERVICES.**

3 (a) GENERAL.—The Secretary of Health and Human
4 Services (hereafter in this Act referred to as “the Sec-
5 retary”) shall revise the practice expense relative value
6 units for drug administration services for years beginning
7 with the year 2005 in accordance with this section. For
8 purposes of this section, “drug administration services”
9 includes chemotherapy administration services, thera-
10 peutic and diagnostic infusions and injections, and such
11 other services as the Secretary specifies.

12 (b) DIRECT COSTS EQUAL TO 100 PERCENT OF
13 CPEP ESTIMATES.—Using the information, including es-
14 timates of clinical staff time, developed in the clinical prac-
15 tice expert panel process, including refinements by Amer-
16 ican Medical Association committees, the Secretary shall
17 estimate the costs of the nursing and other clinical staff,
18 supplies, and procedure-specific equipment (exceeding a
19 cost specified by the Secretary) used in furnishing each
20 type of drug administration service. The Secretary shall
21 utilize without revision the minutes of clinical staff time
22 determined in such process. The Secretary shall convert
23 the information from such process to estimated costs by
24 applying the most current available data on staff salary,
25 supply, and equipment costs, and such costs shall be up-

1 dated to 2005 based on estimated changes in prices since
2 the date of such data.

3 (c) TOTAL PRACTICE EXPENSES.—The Secretary
4 shall estimate the total practice expenses of each drug ad-
5 ministration service by assuming that the direct costs for
6 the service determined under subsection (b) are 33.2 per-
7 cent of such total practice expenses.

8 (d) CONVERSION TO RELATIVE VALUE UNITS.—The
9 Secretary shall convert the total practice expenses deter-
10 mined under subsection (c) to practice expense relative
11 value units for each drug administration service by divid-
12 ing such expenses by the conversion factor that will be
13 in effect for the physician fee schedule for 2005. The rel-
14 ative value units as so determined shall be used in deter-
15 mining the fee schedule amounts paid for drug administra-
16 tion services under section 1848 of the Social Security Act
17 (42 U.S.C. 1395w-4).

18 (e) UPDATES.—For years after 2005, the relative val-
19 ues determined under subsection (d) shall continue in ef-
20 fect except that the Secretary shall revise them as nec-
21 essary to maintain their accuracy, provided that such revi-
22 sions are consistent with the methodology set forth in this
23 section.

24 (f) MULTIPLE PUSHES.—In establishing the payment
25 amounts under this section, the Secretary shall establish

1 the payment amount for intravenous chemotherapy ad-
2 ministration by push technique based on the administra-
3 tion of a single drug. The Secretary shall make the same
4 payment for each additional drug administered by push
5 technique during the same encounter, except to the extent
6 that the Secretary finds that the cost of administering ad-
7 ditional drugs is less than the cost of administering the
8 first drug.

9 **SEC. 4. PAYMENTS FOR CHEMOTHERAPY SUPPORT SERV-**
10 **ICES.**

11 (a) GENERAL.—Beginning in the year 2005, the Sec-
12 retary shall recognize and make payments under section
13 1848 of the Social Security Act (42 U.S.C. 1395w-4) for
14 chemotherapy support services furnished incident to physi-
15 cians' services. For the purposes of this section, "chemo-
16 therapy support services" are services furnished by the
17 staff of physicians to patients undergoing treatment for
18 cancer that were not included in the computation of clin-
19 ical staff costs under section 3(b). Such services include
20 social worker services, nutrition counseling, psychosocial
21 services, and similar services.

22 (b) DIRECT COSTS.—The Secretary shall estimate
23 the cost of the salary and benefits of staff furnishing
24 chemotherapy support services as they are provided in on-
25 cology practices that furnish these services to cancer pa-

1 tients in a manner that is considered to be high quality
2 care. The estimate shall be based on the weekly cost of
3 such services per patient receiving chemotherapy.

4 (c) TOTAL COSTS.—The Secretary shall estimate the
5 total practice expenses of chemotherapy support services
6 by assuming that the direct costs for the service deter-
7 mined under subsection (b) are 33.2 percent of such total
8 practice expenses.

9 (d) CONVERSION TO RELATIVE VALUE UNITS.—The
10 Secretary shall convert the total practice expenses deter-
11 mined under subsection (c) to practice expense relative
12 value units for chemotherapy support services by dividing
13 such expenses by the conversion factor that will be in ef-
14 fect for the physician fee schedule for 2005. The relative
15 value units as so determined shall be used in determining
16 the fee schedule amounts paid for chemotherapy support
17 services under such section 1848.

18 (e) UPDATES.—For the years after 2005, the relative
19 values determined under subsection (d) shall continue in
20 effect except that the Secretary shall revise them as nec-
21 essary to maintain their accuracy, provided that such revi-
22 sions are consistent with the methodology set forth in this
23 section.

1 **SEC. 5. CANCER THERAPY MANAGEMENT SERVICES.**

2 The Secretary shall recognize and establish a pay-
3 ment amount for the service of cancer therapy manage-
4 ment to account for the greater pre-service and post-serv-
5 ice work associated with visits and consultations con-
6 ducted by physicians treating cancer patients compared to
7 typical visits and consultations. The payment amount may
8 vary by the level and type of the related visit or consulta-
9 tion.

10 **SEC. 6. OTHER SERVICES WITHOUT PHYSICIAN WORK REL-**
11 **ATIVE VALUE UNITS.**

12 The Secretary shall develop a revised methodology for
13 determining the payment amounts for services that are
14 paid under the fee schedule established by section 1848
15 of the Social Security Act (42 U.S.C. 1395w-4) and that
16 do not have physician work relative value units, including
17 radiation oncology services. Such methodology shall result
18 in payment amounts that fully cover the costs of fur-
19 nishing such services. Until such time as the methodology
20 for such services is revised and implemented, all such serv-
21 ices shall be protected from further payment cuts due to
22 factors such as shifts in utilization or removal of any one
23 specialty's services that are paid under the fee schedule
24 established by such section 1848 and that do not have
25 physician work relative value units.

1 **SEC. 7. PHYSICIAN SUPERVISION OF SERVICES.**

2 Section 1834 of the Social Security Act (42 U.S.C.
3 1395m), as amended by section 2, is further amended by
4 adding at the end the following new subsection:

5 “(o) SUPERVISION REQUIREMENTS.—If the Sec-
6 retary requires direct supervision of a service by a physi-
7 cian, that supervision requirement may be fulfilled by one
8 or more physicians other than the physician who ordered
9 the service. If the supervising physician is different from
10 the ordering physician for a particular service, the order-
11 ing physician may nevertheless bill for such service pro-
12 vided that the medical records for the service involved
13 identify the supervising physician or physicians.”.

14 **SEC. 8. REPORT TO CONGRESS.**

15 No later than April 1, 2004, the Secretary shall sub-
16 mit to Congress a report on the payment amounts that
17 are projected to be adopted under sections 2, 3, 4, and
18 5 of this Act.

19 **SEC. 9. INSTITUTE OF MEDICINE STUDY.**

20 (a) GENERAL.—The Secretary of Health and Human
21 Services shall request the Institute of Medicine to conduct
22 the study described in this section.

23 (b) BASELINE STUDY.—The first phase of the study
24 shall include the following objectives:

25 (1) An assessment of the extent to which the
26 current Medicare payment system, prior to imple-

1 mentation of the amendments made by this Act, fa-
2 cilitates appropriate access to care by cancer pa-
3 tients in the various treatment settings.

4 (2) The identification of the comprehensive
5 range of services furnished to cancer patients in the
6 outpatient setting, including support services such as
7 psychosocial services and counseling, and rec-
8 ommendations regarding the types of services that
9 ought to be furnished to Medicare patients with can-
10 cer.

11 (3) A discussion of the practice standards nec-
12 essary to assure the safe provision of services to can-
13 cer patients.

14 (4) An analysis of the extent to which the cur-
15 rent Medicare payment system supports the role of
16 nurses in the provision of oncology services and rec-
17 ommendations for any necessary improvements in
18 the payment system in that respect.

19 (5) The development of a framework for assess-
20 ing how the amendments made by this act affect the
21 provision of care to Medicare patients with cancer in
22 the various treatment settings.

23 (c) SECOND PHASE OF STUDY.—After the implemen-
24 tation of the amendments made by this Act, the study
25 shall determine whether and how those amendments af-

1 fected the provision of care to Medicare patients with can-
2 cer.

3 (d) CONSULTATION.—The Institute of Medicine shall
4 consult with the National Cancer Policy Board and organi-
5 zations representing cancer patients and survivors,
6 oncologists, oncology nurses, social workers, cancer cen-
7 ters, and other healthcare professionals who treat cancer
8 patients in planning and carrying out this study.

9 (e) DUE DATES.—

10 (1) The study required by subsection (b) shall
11 be submitted to the Congress and the Secretary of
12 Health and Human Services no later than June 30,
13 2004.

14 (2) The study required by subsection (c) shall
15 be submitted to the Congress and the Secretary of
16 Health and Human Services no later than December
17 31, 2006.

18 **SEC. 10. EFFECTIVE DATES.**

19 (a) GENERAL.—Except as provided in this section,
20 the provisions of this Act shall apply to drugs, biologicals,
21 and services furnished on or after January 1, 2005.

22 (b) REPORTS FROM MANUFACTURERS.—The first re-
23 port by manufacturers required by the provisions of sec-
24 tion 2 shall be submitted no later than October 30, 2004,

1 with respect to sales that occurred in the quarter ending
2 September 30, 2004.

3 (c) SUPERVISION OF SERVICES.—The amendment
4 made by section 7 shall be effective upon enactment.

5 (d) SERVICES OTHER THAN DRUG ADMINISTRA-
6 TION.—The Secretary shall implement the requirements
7 of section 6 no later than January 1, 2005.

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