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108TH CONGRESS
1ST SESSION

H. R. 1622

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 HOUSE OF REPRESENTATIVES

APRIL 3, 2003

Mr. NORWOOD (for himself and Mrs. CAPPS) 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 and otherwise revise the Medicare Program to reform the method of paying for covered drugs, drug administration services, and chemotherapy support services.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Quality Cancer Care Preservation Act''.

SEC. 2. MEDICARE PAYMENT FOR DRUGS AND BIOLOGICALS.

(a) IN GENERAL.—Section 1842(o)(1) of the Social Security Act (42 U.S.C. 1395u(o)(1)) is amended by striking ''95 percent of the average wholesale price'' and inserting ''the payment amount specified in section 1834(n)(2)''.

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

''(n) PAYMENT FOR DRUGS AND BIOLOGICALS.—

''(1) REPORTS BY MANUFACTURERS.—

''(A) IN GENERAL.—Every drug manufacturer shall report to the Secretary, in the manner prescribed in this paragraph, its average sales price (as defined in subparagraph (B)) in the United States during each calendar quarter for drugs and biologicals covered under this part.

''(B) DEFINITIONS.—For purposes of this subsection—

''(i) the term 'manufacturer' means, with respect to a drug or biological, the entity identified by the Labeler Code portion of the National Drug Code of such drug or biological; and

"(ii) the term 'average sales price' means the weighted average of all final sales prices to all purchasers, excluding sales specified in subparagraph (C).

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

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

"(i) prices that are excluded from the calculation of 'best price' under section 1927(c)(1)(C);

"(ii) prices offered to entities that are considered under subparagraph (B)(i) to be the manufacturers of the drugs or biologicals involved;

"(iii) prices offered by a manufacturer to a hospital, nursing facility, hospice, or health maintenance organization;

"(iv) prices to governmental entities; and

"(v) nominal prices offered to bona fide charitable organizations.

"(D) QUARTERLY REPORTS.—Each manufacturer shall submit the report required by subparagraph (A) to the Secretary by electronic means no later than 30 days after the end of a calendar quarter with respect to sales that occurred during such quarter. The Secretary shall prescribe the format and other requirements for the report.

"(E) ENFORCEMENT.—

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

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

may impose a civil money penalty in an amount not to exceed $100,000 on a manufacturer that knowingly provides false information under this paragraph.

''(iii) MANNER OF IMPOSITION OF CIVIL MONETARY PENALTIES.—The provisions in section 1128A (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

''(F) CONFIDENTIALITY OF INFORMATION.—Notwithstanding any other provision of law, information disclosed by manufacturers under this paragraph is confidential and shall not be disclosed by the Secretary in any form other than as specifically authorized by this subsection.

''(2) CALCULATION OF PAYMENT AMOUNT.—

''(A) IN GENERAL.—Except as otherwise provided in this paragraph, the payment amount for a drug or biological furnished during a calendar quarter shall be 120 percent of the average sales price of the drug or biological

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

''(B) METHODOLOGY.—In determining payment amounts under subparagraph (A), the Secretary may, in the Secretary's discretion, use either the average sales price for each drug or biological by specific drug or biological, or a cumulative average sales price based on sales data for all versions of a multiple-source drug that the Secretary, acting through the Food and Drug Administration, has determined are therapeutically equivalent (as evidenced by 'A' ratings in the publication Approved Drug Products with Therapeutic Equivalence Evaluations).

''(C) INCREASE TO REFLECT ADDITIONAL COSTS ATTRIBUTABLE TO STATE AND LOCAL TAXES.—In the case of a drug or biological that was subject to a State or local sales tax or gross receipts tax when administered or dispensed, the payment amount determined under subparagraph (A) shall be increased by the amount of such tax paid with respect to such drug or biological.

"(D) SUBSTITUTION OF HIGHER PAYMENT AMOUNT.—If a physician's, supplier's, or any other person's claim for payment for services under this Act documents that the price paid for a drug or biological was greater than the payment amount determined under subparagraph (A), the actual amount paid shall be substituted for the payment amount determined under subparagraph (A), unless the Secretary determines that the actual amount paid was unreasonable under the circumstances.

"(E) INCREASE FOR BAD DEBT AND CERTAIN OTHER COSTS.—Upon the submission of supporting information, the Secretary shall make an additional payment to a physician or supplier to cover—

"(i) uncollectible deductibles and coinsurance due from Medicare beneficiaries with respect to drugs and biologicals furnished to such beneficiaries; and

"(ii) costs incurred in procuring and billing for drugs and biologicals furnished to Medicare beneficiaries.".

SEC. 3. MEDICARE PAYMENT FOR DRUG ADMINISTRATION SERVICES.

(a) GENERAL.—The Secretary of Health and Human Services (hereafter in this Act referred to as ''the Secretary'') shall revise the practice expense relative value units for drug administration services for years beginning with the year 2005 in accordance with this section. For purposes of this section, ''drug administration services'' includes chemotherapy administration services, therapeutic and diagnostic infusions and injections, and such other services as the Secretary specifies.

(b) DIRECT COSTS EQUAL TO 100 PERCENT OF CPEP ESTIMATES.—Using the information, including estimates of clinical staff time, developed in the clinical practice expert panel process, including refinements by American Medical Association committees, the Secretary shall estimate the costs of the nursing and other clinical staff, supplies, and procedure-specific equipment (exceeding a cost specified by the Secretary) used in furnishing each type of drug administration service. The Secretary shall utilize without revision the minutes of clinical staff time determined in such process. The Secretary shall convert the information from such process to estimated costs by applying the most current available data on staff salary, supply, and equipment costs, and such costs shall be up-

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

(c) TOTAL PRACTICE EXPENSES.—The Secretary shall estimate the total practice expenses of each drug administration service by assuming that the direct costs for the service determined under subsection (b) are 33.2 percent of such total practice expenses.

(d) CONVERSION TO RELATIVE VALUE UNITS.—The Secretary shall convert the total practice expenses determined under subsection (c) to practice expense relative value units for each drug administration service by dividing such expenses by the conversion factor that will be in effect for the physician fee schedule for 2005. The relative value units as so determined shall be used in determining the fee schedule amounts paid for drug administration services under section 1848 of the Social Security Act (42 U.S.C. 1395w–4).

(e) UPDATES.—For years after 2005, the relative values determined under subsection (d) shall continue in effect except that the Secretary shall revise them as necessary to maintain their accuracy, provided that such revisions are consistent with the methodology set forth in this section.

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

the payment amount for intravenous chemotherapy administration by push technique based on the administration of a single drug. The Secretary shall make the same payment for each additional drug administered by push technique during the same encounter, except to the extent that the Secretary finds that the cost of administering additional drugs is less than the cost of administering the first drug.

SEC. 4. PAYMENTS FOR CHEMOTHERAPY SUPPORT SERVICES.

(a) GENERAL.—Beginning in the year 2005, the Secretary shall recognize and make payments under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) for chemotherapy support services furnished incident to physicians' services. For the purposes of this section, ''chemotherapy support services'' are services furnished by the staff of physicians to patients undergoing treatment for cancer that were not included in the computation of clinical staff costs under section 3(b). Such services include social worker services, nutrition counseling, psychosocial services, and similar services.

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

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

(c) TOTAL COSTS.—The Secretary shall estimate the total practice expenses of chemotherapy support services by assuming that the direct costs for the service determined under subsection (b) are 33.2 percent of such total practice expenses.

(d) CONVERSION TO RELATIVE VALUE UNITS.—The Secretary shall convert the total practice expenses determined under subsection (c) to practice expense relative value units for chemotherapy support services by dividing such expenses by the conversion factor that will be in effect for the physician fee schedule for 2005. The relative value units as so determined shall be used in determining the fee schedule amounts paid for chemotherapy support services under such section 1848.

(e) UPDATES.—For the years after 2005, the relative values determined under subsection (d) shall continue in effect except that the Secretary shall revise them as necessary to maintain their accuracy, provided that such revisions are consistent with the methodology set forth in this section.

SEC. 5. CANCER THERAPY MANAGEMENT SERVICES.

The Secretary shall recognize and establish a payment amount for the service of cancer therapy management to account for the greater pre-service and post-service work associated with visits and consultations conducted by physicians treating cancer patients compared to typical visits and consultations. The payment amount may vary by the level and type of the related visit or consultation.

SEC. 6. OTHER SERVICES WITHOUT PHYSICIAN WORK RELATIVE VALUE UNITS.

The Secretary shall develop a revised methodology for determining the payment amounts for services that are paid under the fee schedule established by section 1848 of the Social Security Act (42 U.S.C. 1395w–4) and that do not have physician work relative value units, including radiation oncology services. Such methodology shall result in payment amounts that fully cover the costs of furnishing such services. Until such time as the methodology for such services is revised and implemented, all such services shall be protected from further payment cuts due to factors such as shifts in utilization or removal of any one specialty's services that are paid under the fee schedule established by such section 1848 and that do not have physician work relative value units.

SEC. 7. PHYSICIAN SUPERVISION OF SERVICES.

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

''(o) SUPERVISION REQUIREMENTS.—If the Secretary requires direct supervision of a service by a physician, that supervision requirement may be fulfilled by one or more physicians other than the physician who ordered the service. If the supervising physician is different from the ordering physician for a particular service, the ordering physician may nevertheless bill for such service provided that the medical records for the service involved identify the supervising physician or physicians.''.

SEC. 8. REPORT TO CONGRESS.

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

SEC. 9. INSTITUTE OF MEDICINE STUDY.

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

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

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

mentation of the amendments made by this Act, facilitates appropriate access to care by cancer patients in the various treatment settings.

(2) The identification of the comprehensive range of services furnished to cancer patients in the outpatient setting, including support services such as psychosocial services and counseling, and recommendations regarding the types of services that ought to be furnished to Medicare patients with cancer.

(3) A discussion of the practice standards necessary to assure the safe provision of services to cancer patients.

(4) An analysis of the extent to which the current Medicare payment system supports the role of nurses in the provision of oncology services and recommendations for any necessary improvements in the payment system in that respect.

(5) The development of a framework for assessing how the amendments made by this act affect the provision of care to Medicare patients with cancer in the various treatment settings.

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

fected the provision of care to Medicare patients with cancer.

(d) CONSULTATION.—The Institute of Medicine shall consult with the National Cancer Policy Board and organizations representing cancer patients and survivors, oncologists, oncology nurses, social workers, cancer centers, and other healthcare professionals who treat cancer patients in planning and carrying out this study.

(e) DUE DATES.—

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

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

SEC. 10. EFFECTIVE DATES.

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

(b) REPORTS FROM MANUFACTURERS.—The first report by manufacturers required by the provisions of section 2 shall be submitted no later than October 30, 2004,

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

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

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

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